

AGENDA – August 31, 1999 Business Taxes Committee Meeting
Proposed Amendments to Regulation 1591, *Medicines and Medical Supplies, Devices and Appliances*
Staff's Proposed Regulation 1591, 1591.1, 1591.2, 1591.3, and 1591.4

<p>Action 1 – Consent</p> <ol style="list-style-type: none"> 1. Amended Regulation 1591, <i>Medicines and Medical Devices</i>, except subdivision (e)(7) 2. Proposed Regulation 1591.1, <i>Medical Devices, Appliances and Supplies</i>, except subdivision (b)(4) 3. Proposed Regulation 1591.2, <i>Wheelchairs, Crutches, Canes, and Walkers</i> 4. Proposed Regulation 1591.3, <i>Vehicles for Physically Handicapped Persons</i> 5. Proposed Regulation 1591.4, <i>Medical Oxygen Delivery Systems</i> 	<p>Adopt proposed language as agreed upon by staff and industry.</p>
<p>Action 2 – Application of Tax to Diabetic Patient Aids (Glucose Test Strips and Lancets)</p> <p>Amended Regulation 1591(e)(7), <i>Diagnostic Substances, Test Kits, and Equipment</i> and Proposed Regulation 1591.1(b)(4), <i>Insulin and Insulin Syringes</i></p>	<p>Adopt either: 1) Staff's proposed language (Exhibit 1, pages 17 and 24-25); or</p> <p style="text-align: center;">2) Industry proposed language (Exhibit 1, pages 17 and 24-25)</p>
<p>Action 3 – Authorization to Publish (whichever language is approved)</p>	<p>Direct the publication of the proposed amendments to Regulation 1591 and proposed Regulations 1591.1, 1591.2, 1591.3, and 1591.4 as adopted in the above actions.</p>

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ACTION 1 – Consent Items

Item	Comments
1. Exhibit 1. Pages 1-20, Amended Regulation 1591, <i>Medicines and Medical Devices</i> , except subdivision (e)(7)	Accept proposed language agreed upon by staff and industry.
2. Exhibit 1. Pages 20-25, Proposed Regulation 1591.1, <i>Medical Devices, Appliances and Supplies</i> , except subdivision (b)(4)	Accept proposed language agreed upon by staff and industry.
3. Exhibit 1. Pages 25-28, Proposed Regulation 1591.2, <i>Wheelchairs, Crutches, Canes, and Walkers</i>	Accept proposed language agreed upon by staff and industry.
4. Exhibit 1. Pages 29-31, Proposed Regulation 1591.3, <i>Vehicles for Physically Handicapped Persons</i>	Accept proposed language agreed upon by staff and industry.
5. Exhibit 1. Pages 31-37, Proposed Regulation 1591.4, <i>Medical Oxygen Delivery Systems</i>	Accept proposed language agreed upon by staff and industry.

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Action Item	Staff Proposed Language	Industry Proposed Language
<p>ACTION 2,</p> <p>“Diagnostic Substances, Test Kits, and Equipment”</p> <p>Exhibit 1, Page 17</p>	<p>Amended Regulation 1591(e)(7):</p> <p><i>(7) Diagnostic Substances, Test Kits, and Equipment.</i> Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment, they are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines for the purposes of the exemption provided under Section 6369.</p> <p>Tax also applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether or not they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.</p>	<p>Amended Regulation 1591(e)(7):</p> <p><i>(7) Diagnostic Substances, Test Kits, and Equipment.</i> Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment, they are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines for the purposes of the exemption provided under Section 6369.</p> <p>Except as otherwise provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether or not they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.</p>

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Action Item	Staff Proposed Language	Industry Proposed Language
<p>“Insulin and Insulin Syringes”</p> <p>Exhibit 1, Pages 24-25</p>	<p>Proposed Regulation 1591.1(b)(4):</p> <p>(4) Insulin and Insulin Syringes. “Insulin” and “insulin syringes” furnished by a pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369(e). As such, the sale or use of insulin and insulin syringes furnished by a pharmacist to a person for treatment of diabetes, as directed by a physician, is exempt from tax.</p> <p>However, the exemption provided under Section 6369(e) does not apply to the sale or use of glucose monitoring systems. Blood glucose monitors, glucose test strips, lancets, and other related items are used by a patient to monitor and test his or her blood sugar level, they are not applied to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease. Since the system and related items do not qualify as medicines or come under the exemption provided by Section 6369(e), their sale or use is subject to tax regardless of whether or not they are furnished pursuant to the direction of a licensed physician.</p>	<p>Proposed Regulation 1591.1(b)(4):</p> <p>(4) Insulin and Insulin Syringes. “Insulin” and “insulin syringes” furnished by a pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369(e). As such, the sale or use of insulin and insulin syringes furnished by a pharmacist to a person for treatment of diabetes, as directed by a physician, is exempt from tax.</p> <p>Glucose test strips and skin puncture lancets furnished by a registered pharmacist that are used by a diabetic patient to determine his or her own blood sugar level and the necessity for and amount of insulin and/or other diabetic control medication needed to treat the disease in accordance with a physician’s instructions are an integral and necessary active part of the use of insulin and insulin syringes or other anti-diabetic medications and, accordingly, are not subject to sale or use tax pursuant to subsection (e) of Section 6369. These medical supplies are not medicines and do not qualify for sales or use tax exemption under subsections (a) or (b) of Section 6369.</p>

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Action Item	Staff Proposed Language	Industry Proposed Language
ACTION 3, Authorization to Publish (whichever language is approved)		

Issue Paper Number 99-041



BOARD OF EQUALIZATION
KEY AGENCY ISSUE

- ☐ Board Meeting
- ☒ Business Taxes Committee
- ☐ Customer Services Committee
- ☐ Legislative Committee
- ☐ Property Tax Committee
- ☐ Technology & Administration Committee
- ☐ Other

REGULATION 1591 - MEDICINES AND MEDICAL SUPPLIES, DEVICES AND APPLIANCES

I. Issue

Should Regulation 1591 be amended to reorganize the current version, incorporate industry's proposed amendments, and rewrite various sections to clarify the application of tax on the sales of medicines and related items?

II. Staff Recommendation

Staff recommends that Regulation 1591 be amended to reorganize Regulation 1591 into five separate regulations (Exhibit 2 through Exhibit 6) with the incorporation of industry's proposed language and suggestions, when appropriate. Staff also recommends that the reorganization include: 1) information from various annotated legal opinions; 2) clarification that the sale or use of replacement parts for kidney dialysis machines is exempt; 3) clarification that "physician" also includes a podiatrist for the purposes of section 6369.2; and 4) clarification that the use of sample clinical trial drugs is not subject to tax when such samples qualify as medicines, including patches impregnated with medicines. Also, staff does not believe statutory authority exists to amend the regulation to exempt the sale or use of diabetic patient aids.

III. Other Alternative(s) Considered

- Alternative 1
As proposed by the California Pharmacists Association, amend and reorganize Regulation 1591 in the same manner as described in staff's recommendation; however, the alternative also provides an exemption for the sale or use of diabetic test aids.

Issue Paper Number 99-041

IV. Background

Included with its April 12, 1999 letter to the Program Planning Manager, the California Pharmacists Association submitted proposed amendments to Regulation 1591 for consideration by staff and discussion at the August 31, 1999 Business Taxes Committee meeting. On May 21, 1999, staff received correspondence from Baker & McKenzie, Attorneys at Law, providing comments and suggesting minor revisions to the California Pharmacists Association's proposed regulatory language.

On June 9, 1999, staff met with interested parties to discuss the proposed amendments to Regulation 1591. As a result of the meeting, staff agreed to reorganize the regulation and to incorporate a number of the amendments proposed by the California Pharmacists Association and to address the concerns noted by Baker & McKenzie.

On July 6, 1999, staff received correspondence from Ernst & Young LLP that proposed an amendment to Regulation 1591 to address the taxability of drugs dispensed in clinical trials during the Food and Drug Administration's approval process.

On July 6, 1999, the California Pharmacists Association submitted a restatement of their previously proposed amendments, including the information inadvertently omitted from their initial draft and a response to staff's analysis of the proposed amendments (Attachment 1).

After reviewing the proposals submitted by the California Pharmacists Association and Ernst & Young LLP, staff revised its initial *Discussion for Issue Paper* and provided a copy of it and the two proposals to interested parties. On August 6, 1999, staff received a proposed revision from Ernst & Young LLP to amend Regulation 1591 subdivision (b)(7) and replace the language originally submitted for proposed subdivision (b)(8) with language to expand the current exemption provided for the sale or use of programmable drug infusion devices to include other delivery systems and the related support equipment (Attachment 2). In subsequent discussions with staff, Ernst & Young LLP narrowed their interest specifically to an exemption for the sale and use of patches impregnated with medicines.

The following discussion provides staff's comments and suggestions concerning proposed amendments to Regulation 1591 and, when applicable, incorporates the comments and proposed regulatory language provided in the correspondence received from interested parties.

Discussion – Sales and Use Tax Law Section 6369

Under existing law, except where specifically exempted by statute, sales or use tax is imposed on all retailers for the privilege of selling tangible personal property at retail in this state. Section 6369 provides that sales of medicines, when prescribed and sold or furnished under certain conditions for the treatment of a human being, are exempt from sales and use tax. Although a drug, item, device, or apparatus may be prescribed by a physician for the treatment of a patient, for the sale to be exempt from tax, the item must qualify as a "medicine" under section 6369.

Section 6369 was added to the Sales and Use Tax Law in 1961 to exempt the sale or use of any substance or preparation intended for use by external or internal application to the human body and commonly recognized as a "medicine." "Medicine" was defined to mean "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, treatment,

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or prevention of disease when prescribed by a person authorized to prescribe and dispensed by a prescription filled by a registered pharmacist." As originally enacted in 1961, section 6369 (Stats. 1961, ch. 866) limited its exemption for medicines to those prescribed by an authorized person and dispensed on prescription. This exemption is now contained in subdivision (a)(1) of the current version of Regulation 1591. In 1962 (Stats. 1962, ch. 7), the Legislature added the exemptions now contained in Regulation 1591, subdivision (a)(2), covering medicines supplied by a physician and surgeon or podiatrist to his or her own patients and subdivision (a)(3), covering prescribed medicines furnished to patients in a county or licensed hospital.

In 1963 (Stats. 1963, ch. 716), the Legislature restructured section 6369 by numbering the different types of exempted medicines, adding exemptions contained in subdivisions (a)(4) and (a)(5), and changing the definition of medicines. The definition of medicines previously included "any drug defined pursuant to section 4031 of the Business and Professions (B&P) Code," which itself included "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals," as well as other articles. As the definition contained within B&P Code section 4031 could have been construed to also apply to durable medical equipment, the reference was deleted. Not including such items in the medicine exemption is believed by staff to be a clear indication of legislative intent at that time.

Over the years, various bills were introduced to expand the exemption, but were unsuccessful. During the 1975-76 Legislative Session, a number of bills were introduced to expand the sales and use tax exemption for medical devices, each bill dealing with a particular device. In response to these bills, the Assembly Revenue and Taxation Committee appointed a staff task force charged with undertaking a comprehensive review of the various medical devices that might be considered for exemption. The task force developed a report that specifically recommended against changing the taxable status of durable medical equipment, medical instruments, and other patient aids. The following is an excerpt from that report:

"There is great difficulty in drafting language specific enough to exempt some items and exclude others. The alternative of opening up all devices for exemption would represent a significant revenue loss and erosion of the sales tax base. Rather than try to draw elaborate distinctions justifying the exemption of some items and not others (a major problem under current law), it would be better not to venture into this category."

Considering the original enactment of the medicine exemption and the amendments that have followed, it appears to staff that the Legislature did not intend an expansive construction of the exemption beyond the explicit wording of section 6369. Although several related items have been incorporated by the Legislature into the medicine exemption, including certain medical devices and equipment, such inclusion has been on a specific basis. In general, the exemption has been expanded to apply to specific items of equipment, with emphasis more on what the device does rather than what it is called. In some areas, certain items are included as medicines while other items that perform the same function are not. For example, "sutures" are included, but "surgical fabric" is not, though both appear to perform the same function. Defined "implants" are included, but "dentures" are specifically excluded. It appears that the Legislature has kept tight control over the medicine exemption and that there is no statutory basis for the exemption beyond that actually provided by section 6369. Keeping this in mind, it is staff's position that any proposed amendments to Regulation 1591 should mirror the provisions of the applicable statutory law.

As provided in its July 6, 1999, "*Response to the Board's Staff Discussion on Proposed Changes to Regulation 1591*" (response), the California Pharmacists Association states they are not in agreement with staff's interpretation that the Legislature intended a "narrow construction" of Section 6369. The

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response explains that the nature of the items added after the 1975-76 Legislative session and the development of the task force reveal that the amendments of October 1977 through October 1983 added broad categories of items to the relevant law sections. The response also states:

"It is not until the amendments of August 1988, effective October 1989 and thereafter, that specific, limited device and appliance exemptions began to be added. These took the form of 'custom-made biomechanical foot orthoses' in October 1989, white canes for the legally blind (but which met the previous exemption definition of a cane) in 1994; coronary and intra-aortic balloon catheters in June 1999; and reflected vehicle code changes in Oct. 1998.

"The Assembly Revenue and Taxation Committee task force report recognized that some durable medical equipment, medical instruments and other patient aids might well have qualified as exempt items. The Association concurs with the task force's opinion that a blanket exemption of all medical devices, medical equipment and patient aids would raise the possibility of a significant revenue loss, were such an exemption to occur. Nevertheless, it seems unconscionable that, in a period of nearly 24 years since that report, no effort has been made to attempt such a task. It seems to the Association, that enough industry and professional expertise exists that substantial definition of devices and other patient aids that would be acceptable as exemptions could be made."

Discussion - Proposed Regulatory Amendments

As stated previously, the California Pharmacists Association, hereafter referred to as industry, submitted proposed amendments to Regulation 1591 intended to generally reorganize the regulation, clarify the application of tax, incorporate common industry terms, delete perceived obsolete terms, and provide a basis to accommodate the dispensing of specific devices by medical supply dealers, including a "medical device retailer." Industry's proposal also incorporates the opinions contained within various annotations, provides additional definitions, references "dangerous drugs" and "dangerous devices," and incorporates current B&P Code references. Since recent amendments to Regulation 1591 incorporated most of the current and applicable B&P Code sections, these proposed revisions are not at issue and do not require a discussion.

In its July 6, 1999 response, industry explains the intent behind its proposed reorganization of Regulation 1591. As explained, the proposed amendments are intended to provide a "general" section that can be reviewed by all parties affected. A definition section and sections based on subject matter (termed "subregulations" by staff) are also included to provide interested parties relevant sections that focus on a specific type of medicine or device and the applicable requirements necessary for the sale or use to be exempt from tax. There was no intention on the part of industry to delete existing sections of the regulation.

Discussion - Industry's Proposed Revisions to Existing Subdivision 1591(a)

In Regulation 1591, the second paragraph of existing subdivision (a) begins:

"Tax does not apply to sales of medicines for the treatment of a human being which medicines are...."

Industry's proposed subdivision (a) expands the section to include the following:

"Tax does not apply to sales of medicines for the diagnosis, cure, mitigation, treatment or prevention of disease of a human being, which are commonly recognized as a substance, preparation for that use, and which medicines are...."

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Industry's proposed language combines language from the current version of subdivision (a) and subdivision (b)(1). During the June 9, 1999 meeting, industry explained that the combining of the language from subdivision (a) and subdivision (b) was intended to provide additional clarification and emphasis. Staff believes that staff's reorganization of Regulation 1591 will provide the clarification and emphasis believed necessary.

Industry also proposes a revision to current subdivision (a)(1) to include additional language as follows:

"(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines and are dispensed on prescription filled by a ~~registered~~ pharmacist in accordance with law, or as otherwise set forth in these regulations, or...."

Industry states the proposed revision to subdivision (a)(1) is intended to remove the obsolete term "registered" and to "accommodate the dispensing on prescription of prosthetic or orthotic devices by a medical supply dealer, as well as the furnishing of wigs." There are no proposed revisions to the current version of subdivisions (a)(2) through (a)(5); however, industry's proposed reorganization moves subdivision (a)(6) to proposed "subregulation" 1591.1, *Drugs and Medicines*, and inadvertently deletes subdivision (a)(7).

As current subdivisions (a)(1) through (a)(7) are essentially a restatement of statutory law, it appears that any proposed revisions would need to reflect the provisions contained within the existing statutory law. With regard to deleting the term "registered" from subdivision (a)(1), staff agrees that the term can be deleted from subdivision (a)(1) since it is recognized as obsolete and, as noted by industry, was deleted in 1998 from the controlling statutes for pharmacist licensure. Deletion of the term does not appear to be contrary to the intent of section 6369.

Regarding the proposed revision to subdivision (a)(1) to add the words, "or as otherwise set forth in these regulations..."--addition of this proposed language could result in confusion and an implied exemption for devices, other than those specifically provided for by statute, that are dispensed by other than a pharmacist as provided by law. It appears that the proposed revision is intended to provide an exemption for medical devices dispensed through a medical device retailer where other than a pharmacist fills the respective prescriptions. Although staff is aware that "dangerous devices" are currently dispensed through a medical device retailer, not all have pharmacists on duty. When relying on the general provisions of section 6369, the item must be dispensed by a pharmacist for the sale to come within the exemption. Thus, the dispensing of an otherwise qualifying device by a medical device retailer will not qualify for exemption unless the person dispensing the device is a pharmacist, or the sale comes within a specific statutory exemption that does not require dispensing by a pharmacist.

As for the specific exemptions provided for orthotic, prosthetic, and mammary prostheses devices, the statute does not require that the devices be dispensed by either a pharmacist or a "medical device retailer." Even though the B&P Code may provide limitations on who may dispense "dangerous devices," no such limitation exists under section 6369. Adding the proposed language would introduce a new restriction on what type of entity can dispense orthotic, prosthetic, and mammary prostheses devices under section 6369. Subdivisions 6369 (f) and (g) both provide conditions where the devices discussed within are deemed to be dispensed on prescription whether or not the devices are furnished by a pharmacist. There is no restriction in those subdivisions on who may sell the devices. The exemption exists as long as the conditions of the statute are met.

However, in order to provide additional clarification regarding retailers who may sell orthotic, prosthetic, and mammary prostheses devices, staff included a listing of the type of retailers that regularly

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sell such devices in staff's proposed reorganization of the regulation. Although the listing is not intended to be all-inclusive, it should provide the clarification desired.

With regard to current subdivision (a)(7), industry's proposed reorganization inadvertently deleted this subdivision. This was confirmed at the June 9, 1999 meeting and in industry's recent correspondence. Accordingly, industry included the language of subdivision (a)(7) in their second proposal. Staff's reorganization of Regulation 1591 will also retain the language of this subdivision.

Discussion - Industry's Proposed Subdivision 1591(b), (c), and (d)

Industry proposes the addition of the following paragraphs as new 1591(b) through (d):

"(b) Any medicine which is dispensed, furnished, or administered for the care of a patient in compliance with any of the conditions set forth in paragraph (a)(1) through (a)(5) above shall be deemed to be a critical component in the delivery of medically necessary care to that patient.

"(c) Any medicine which is tax exempt, when sold or furnished under any one of the conditions set forth in subparagraph (a)(1) through (a)(5) above, is equally tax exempt if sold or furnished under any of the other conditions set forth above.

"(d) Sales of medicines not meeting the definitions in subparagraph (b) sold to or by health practitioners or facilities are not exempt from tax, provided, however, if subsequent sales to patients meet the applicable requirements set forth in subparagraph (a) above, the sales would be exempt."

Regarding proposed subdivision (b), the law does not require the Board to decide whether a medicine is a "critical component" in the delivery of medically necessary care. Current statutory provisions (section 6369(a)) already make it clear that the sale or use of medicines is exempt when sold or transferred in one of the ways provided for in that section. The statute does not provide a requirement that the medicine meeting the conditions of section 6369(a) be deemed a critical component in the delivery of medically necessary care, and the inclusion of that requirement would introduce a new restriction on the exemption.

In their July 6, 1999 response, industry states:

"We agree with the logic of staff that the individual medical provider is the one who should make such a determination. We feel, however, that the fact that the medical provider who orders a specific "medicine" for his or her patient has made such a decision and that that "medicine" is a critical component of medically necessary care. To argue otherwise, is to accuse the medical providers of ordering unnecessary medical care.

"We think that the court has held a similar position, as in the case of *Purdue Frederick Co. v. State Board of Equalization* (1990) 218 Cal.App.3d 1021. Here, an antiseptic skin cleanser used by hospitals on patients and for preoperative scrubbing by operating personnel and hand cleansing by hospital [personnel] caring for patients was found to be a tax-exempt medicine since the cleanser, in all such uses, is applied to the human body in the mitigation and prevention of disease. The application of the cleanser by hospital personnel to their own bodies was held to benefit the patient and constitute a critical component of the patient's treatment. If the product is a critical component of patient care when applied to hospital personnel, a product supplied to the patient, in conformance with any of the requirements of (a)(1) through (a)(5) is, and should be so declared, a critical component in the delivery of medically necessary care to that patient. This court decision was the basis for the inclusion of the "critical component" language by CPhA."

Although industry's response provides more insight into the reason for including proposed subdivision (b), staff believes that this inclusion could confuse and imply provisions that are not intended. The sale of an item that does not meet the statutory definition of medicine cannot be exempt under section 6369 whether the item is deemed a critical component in a patient's care or not, while the sale of an item that does meet the statutory definition of medicine and the other statutory requirements is exempt whether the item is deemed a critical component in a patient's care or not.

As for subdivision (c) in industry's proposal, industry's response explains:

"The proposed language of (c) is an attempt to indicate to the user that any 'medicine' as contemplated under Section 6369, which may be tax-exempt under one of the conditions of (a), for instance, furnished by a licensed physician, dentist, or podiatrist to his or her own patient [(a)(2)], would be equally tax-exempt if prescribed for the treatment of a human being by a person authorized to prescribe the medicine and dispensed on prescription by a pharmacist in accordance with law [(a)(1)]. The Association is not sure that persons affected by the regulation would be aware of this fact, absent a statement to that effect."

Staff understands the basis of industry's proposed paragraph, but does not believe that its inclusion is necessary or as beneficial as industry believes. The listings referenced in Regulation 1591 subdivision (a) already clarify the alternatives under which an exemption applies with an "or" between each subparagraph.

Also, it appears that subdivision (d) provides that medicines "deemed to be a critical component in the delivery of medically necessary care" are only exempt when furnished by a physician or other such practitioner, not when sold to or by a health practitioner or facility. This does not mirror the provisions of section 6369. Industry, in its July 6, 1999 response, states:

"The proposed language of Regulation 1591(d) was intended to recognize that there could be instances in which the sale of a product might be subject to sales tax at the time of sale but subsequent usage may be one which is exempt from tax. The scenario we had in mind was one in which items might have been sold to a hospital or other health facility for its own use but which subsequently were provided to a patient for that patient's sole use. While this is a reasonably valid scenario, we are not able to identify products which might easily fall into such a category. We realize that the rationale for (d) may be marginal and that its inclusion may not be warranted."

Although staff now understands industry's basis for including the proposed paragraphs, staff continues to believe the paragraphs are unnecessary for the purposes of interpreting and clarifying the provisions of section 6369.

Discussion - Definitions, Industry's Proposed Subdivision 1591(e)

Subdivision (e), of industry's proposed language, provides a grouping of current regulatory definitions and the inclusion of new definitions industry believes necessary. Other than where industry has chosen to place the subcategory "definitions" within the body of the proposed draft, staff has no objection to the inclusion of a section specifically for definitions. Grouping all definitions in one place is logical and is consistent with the organization of other regulations.

Other than existing subdivision (a)(7), it does not appear that the definitions found within the current version of Regulation 1591 have been deleted--just rearranged. However, along with adding new definitions, industry has proposed expanding the definitions currently contained within the regulation.

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Although expansion of the definitions is believed by industry to facilitate understanding and provide support for other sections of the proposed regulations, staff does not believe that statutory authority currently exists to add and/or expand some of the definitions as proposed. Also, it appears that if statutory authority does exist, some of the expanded language may be confusing to the reader.

For example, industry proposes to expand the definition of medicine currently contained within subdivision (b) of Regulation 1591. Industry's proposed definition, subdivision (e)(1) of industry's proposal, provides that medicines means and includes:

"a. ~~a~~Any substance or preparation, including dangerous drugs, intended for use by external or internal application to the human body, and its parts, including blood and urine, in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use."

Industry states that revisions included in proposed subdivision (e)(1)a "provide for dangerous drugs and to clarify that the definition applies to body parts as well." Staff believes that the addition of "dangerous drugs" ... "and its parts, including blood and urine," to the current regulatory definition of medicines, requires a legislative change. The language contained in the current version of Regulation 1591 mirrors the statutory definition of "medicines," as defined in section 6369. Industry's proposal is broader than the statutory definition and expands the statutory definition. The proposed revisions provide an expansion of the definition of medicine to items the Board and/or the Legislature have previously rejected.

The exemption provided by section 6369 is for medicines as defined, which is for external or internal application to the human body. The proposal is to expand the definition to include items applied to materials that are no longer part of the human body. As written, the proposed definition includes items such as urine and blood after they are withdrawn from the human body. Any substance or preparation applied to these "body parts" and used in the diagnosis of a condition or for treatment would be considered a "medicine." Current statutory law provides for substances or preparations applied to the human body as a whole, not its parts when such parts are no longer connected to, or contained within, the human body. Such items are no longer part of the human body and do not come within the statutory language.

In its July 6, 1999 response, industry states:

"Staff has taken issue with the proposed additional language, and its parts, including blood and urine, to the current regulatory language. They state that they believe that current statutory law provides for substances or preparations applied to the human as a whole, not its parts. They believe the Legislature distinguishes between the whole body and its parts when that is the Legislature's intent.

"How then, do they account for the use of exempt medicines, such as a barium enema which has no effect on the human body, but only affects a part, the digestive tract, or, even more finely defined, the intestinal tract, and serves an internally applied diagnostic tool to the physician. The enema has been furnished to a health facility for the treatment of a person pursuant to the prescription of that person's physician.

"How do they account for the application of medications to a person's eye, not to his or her whole body?

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"What is the rationale for considering an artificial hand as applied to the whole body, rather than as a prosthesis to replace a part, the hand?

"CPhA is sure that the actions of the Legislature in including any of the above examples as exempt items were not based on the concept of applying substances, preparations or devices to the human body as a whole, but, explicitly recognized the body part concept. "

Staff understands the analysis made by industry; however, there appears to be a misunderstanding concerning staff's discussion of body parts. With regard to industry's question as to whether a barium enema, that only affects a part of the human body, is considered as applied to the human body as a whole, the answer is yes. Although the barium enema may be applied to a specific part of the human body, it is nevertheless applied to the human body in the general sense as well as the technical sense.

In its analysis, staff did not intend to imply that a medicine must be applied to the "total" body for the sale or use to qualify for exemption from tax, and that has never been the position of staff. On the contrary, medicines applied to a portion of the body, such as the eyes, are considered to be applied to the human body when the eyes are, at the time of application, an integrated component of the human body. The eyes are not separated from the body as a whole, as is the case with blood and urine that is withdrawn or expelled from the human body, before the substance is applied. In short, if within and inter-connected with all other organs of the human body, the "part" is simply one piece of the human body. Once it is no longer within and inter-connected, the former body part cannot, by itself, be regarded as a human body.

It appears that industry's proposed revision would have the unintentional effect of providing an exemption for the sale or use of "chemical reagents," an issue previously considered by the Board. In the case *Eisenhower Medical Center, et al. V. State Board of Equalization, et al.*, the Board rejected the interpretation that application of a substance to body parts, e.g., tissue samples, qualifies for exemption from tax in the same manner as a substance that is applied to the human body. The Board is currently defending that interpretation in court, and it thus would appear that adopting an interpretation to the contrary would undermine the Board's litigating position.

As considered in the case of Eisenhower Medical Center, reagents may be used to diagnose diseases and determine the proper treatment, or to monitor the levels of medication in a patient. It appears that all of the various diagnostics and monitoring procedures are performed only pursuant to a physician's order, on either a prescription pad or a laboratory request form. However, the diagnostic substances are applied externally to parts of the human body, i.e., cells, tissues or organs that are no longer within and inter-connected to the human body, not by "external or internal application to the human body" as provided in section 6369(b). As such, the reagents do not qualify as medicines for sales and use tax purposes. Reagents are applied to tissue, serum, blood or urine samples which have been removed or expelled from the patient and thus are no longer an integrated part of the human body.

Industry's April 28, 1999 proposal also provides an avenue for exempting sales of "glucose test strips, lancets, and alcohol wipes" used by diabetic patients to determine blood sugar levels, as provided in proposed subdivision 1591.1(b)(1) of proposed "subregulation" 1591.1. Industry's July 5, 1999 proposal expands the proposed exemption to include blood monitoring equipment and related supplies in addition to glucose test strips. Monitoring blood glucose requires three elements, the blood glucose monitor, test strips, and lancets. The patient uses the lancet to draw a small amount of blood that, in turn, is "dropped" onto the test strip. The test strip is then "read" by the monitor. Although the point of the lancet comes in contact with the body, the monitor and the test strips are not "applied" to the human body as that term is used for the purposes of sales and use tax as discussed above. Even if staff were to

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agree with industry's concept that parts removed or expelled from the human body are still considered the "human body," the glucose monitoring equipment and some of the related supplies never come in contact with blood or urine. Although the test strip does come in contact with the blood or urine when such fluids are dropped onto the strip, the test strip itself does not appear to meet the definition of a medicine as provided under section 6369(b).

Legislation has previously, but unsuccessfully, been sought to exempt the sales of these items. In enacting Assembly Bill 681 (Stats. 1952, Ch. 1530), the Legislature excluded insulin "paraphernalia" (patient aids) when providing an exemption for sales of insulin syringes. Senate Bill 2049 was introduced in February 1996 to exempt from taxes the sale and purchase of "glucose test strips, lancets, and blood glucose monitors." The bill was not enacted. Without the passage of the bill, the inclusion of the proposed language adds a provision that lacks statutory basis and that potentially could imply an exemption from tax for the sale or purchase of a larger class of laboratory and home testing kits.

As for adding the term "dangerous drugs" to the statutory-based definition of medicines, this proposal is beyond the scope of section 6369. Currently, the provisions of section 6369 and other related sections do not reference "dangerous drugs." Even though this term is significant to interpreting the provisions of the B&P Code, no such significance exists under the Sales and Use Tax Law. Specific inclusion of the term in the regulatory definition of medicines not only appears unnecessary, but could also restrict the definition in a manner that staff believes is not required under the Sales and Use Tax Law.

In their July 6, 1999 response, industry states:

"Staff has commented that some of CPhA's definitions may be confusing to the reader. They give as an example the inclusion of the term dangerous drug in the definition of a medicine. While this may seem confusing to the staff, every pharmacist, physician, dentist, podiatrist, optometrist, chiropractor, health facility, and current medical supply dealer is fully aware of the meaning and significance of this term. Who is left to be confused? Whom ever they are, they are a tiny minority of users affected by these regulations and our proposed language. We feel it is the responsibility of the BOE staff to interpret and clarify the statute, through the regulatory process. Staff has argued that the regulation should mirror the language provided in Section 6369(pg. 8). CPhA believes to the contrary and feel that a regulation should reflect the intent of the Legislature. As circumstances change, staff should be introducing regulatory changes which accommodate these changing circumstances but which continue to reflect the intent of the Legislature. If the only approach is to mimic exactly the statutory language, there is no need for the regulation.

"As the Association has indicated earlier, our proposed addition of the term dangerous drugs is one of education and recognition of the health care provider's world. If the exemption from sales tax applies to the sale of certain dangerous drugs and dangerous devices, we feel it is sound public policy to alert the users of these regulations that other controlling conditions may also apply. "

Staff assumes that the other controlling conditions referred to by industry are those contained within the B&P Code or other such law. Although it appears to be good policy to alert the reader to other laws that may control their sale of items, such controls do not exist pursuant to the Sales and Use Tax Law. Implying or stating otherwise is to imply that a restriction exists to limit the exemption for sales of otherwise qualifying devices and drugs.

Further, a substance, whether deemed a dangerous drug or not, intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and

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which is commonly recognized as a substance or preparation intended for such use, will qualify as a medicine for sales and use tax purposes. A medicine, as defined, does not need to be a "drug," just a "substance" or "preparation." This agency and the courts have long recognized that such "substance" and "preparation" does not need to be a "drug."

Industry proposes adding subdivision (e)(1)b to the definition of medicines. As proposed, medicines means and includes,

"b. Any medical supply, prosthetic or orthotic device, medical device or appliance, meeting the above definition of a medicine, and which meets the requirements of the applicable regulation sections which follow."

Industry's stated purpose for the above-proposed revision is to "facilitate reformatting the regulation into individual components which affect specific classes or categories of medicines." Staff believes that with the inclusion of this additional proposed language and the other proposed revisions to the definition of medicine, any medical supply, medical device, or appliance that meets the newly proposed regulatory provisions would qualify as a medicine. Section 6369 defines the term "medicine" for purposes of the exemption. Although other statutory provisions have been enacted to expand the exemption for specified devices under certain conditions, there is no statutory basis for expanding the definition of medicine by regulation beyond the statutory definition, as proposed by industry.

Regarding proposed definitions subdivisions (e)(2), (e)(3), and (e)(5), these subdivisions are restatements of existing regulatory definitions, as stated by industry. Proposed subdivisions (e)(4), *Physicians...* (e)(6), *Medical Device Retailer*; (e)(7), *Dangerous Device*; (e)(8), *Medical Supplies*; and (e)(9), *Dangerous Drugs* are new definitions. It is not clear to staff why these are necessary, particularly since their inclusion may result in unwarranted implications and confusion. As written, these definitions, coupled with other proposed regulatory language, imply an exemption or restriction where one is not statutorily provided for sales and use tax purposes.

For example, industry states that proposed subdivision (e)(6), *Medical Device Retailer* is added to reflect statutory requirements for places that may sell, fit, or furnish medical devices. The statutory requirements referred to are provisions of the B&P Code, not the Revenue and Taxation Code. Board regulations are not intended to interpret other laws. Staff believes that since there is nothing in section 6369 concerning a "medical device retailer," there is no basis for the Board to restate these requirements. Adopting this definition could cause the exemption to be lost in areas where it is now available. It is likely that some of the vendors of such devices, whose sales are now exempt under section 6369(f) and (g), would not qualify as "medical device retailers" under industry's proposed definition, resulting in loss of the exemption for their sales. There is no basis for restricting the exemption in this manner.

In its July 6, 1999 response, industry states:

"The Association understands the reluctance of staff in the use of the terms Physicians, (e)(4); Medical Device Retailer, (e)(6); Dangerous Device, (e)(7); Medical Supplies, (e)(8); and Dangerous Drugs, (e)(9). They state that adopting, for example, the definition of Medical Device Retailer might cause the exemption to be lost in areas where it is now available. CPhA notes that persons or companies currently making sales of 'dangerous devices,' as defined by the Business and Professions Code, but not qualified by licensure as a Medical Device Retailer are conducting illegal sales. An exemption to the collection of sales tax rewards the retailer for his or her illegal act. CPhA hardly thinks that the loss of exemption is contrary to legislative intent. Continuing to grant such an exemption is bad public policy."

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Staff understands industry's reason for including specific definitions. However, industry is asking that the Board enforce the provisions of the B&P Code by restricting an exemption provided in the Revenue and Taxation Code. There is no basis in the R&T Code for such restriction.

Discussion - Industry's Proposed "Subregulations"

Through the proposed reorganization and revisions to Regulation 1591, industry has grouped subject matter. For purposes of this discussion, we refer to these groupings as "subregulations." Staff agrees with industry that reorganizing the regulation will lead to better understanding of the regulation. A majority of industry's proposed language is a restatement of the applicable language in the current version of Regulation 1591; accordingly, we will discuss only those subregulations containing significant deletions or additions.

"Regulation 1591.1, Drugs and Medicines"

Industry's April 28, 1999 proposed subregulation 1591.1 provides:

"The following items are exempt unless otherwise indicated:

"(a) Drugs and medicines, including both dangerous drugs and those which do not qualify as such, but which meet any of the requirement of Section 1591 (a)1 through (a)5....

"(b) Insulin and Insulin syringes furnished by a pharmacist to a person for treatment of diabetes as directed by a physician. These items shall be deemed to be medicines dispensed on prescription within the meaning of Section 6369.

"1. Glucose test strips, lancet and alcohol wipes used by diabetic patients to determine his/her blood sugar level are exempt."

For proposed Regulation 1591.1 (a), industry segregates the subject matter into two types: items it believes to be a drug or medicine and, as such, exempt; and items that do not qualify as a drug or medicine. In industry's proposal, the examples appear to stand alone.

Industry's proposed 1591.1 (b) addresses insulin and insulin syringes and restates current regulatory language. However, as noted above, proposed 1591.1 (b)1 provides that "glucose test strips, lancets and alcohol wipes used by diabetic patients to determine his/her blood sugar level are exempt." As stated previously, several bills have been introduced in the Legislature to exempt the sale of such items, but have not been enacted. Section 6369 does not include these "patient aids" in the definition of "medicines." Accordingly, staff does not believe that statutory authority exists to exempt the sale of these items as proposed.

Industry's proposal of July 6, 1999, expands on the patient aids covered by proposed Regulation 1591.1(b). As proposed, the subdivision provides:

" (b) Insulin and Insulin syringes furnished by a pharmacist to a person for treatment of diabetes as directed by a physician. These items shall be deemed to be medicines dispensed on prescription within the meaning of Section 6369.

"1. Blood monitoring equipment, glucose test strips and related supplies used by diabetic patients to determine his/her blood sugar level are exempt."

As noted above, industry's July 6, 1999 proposal differs from that initially submitted. Industry's second proposal includes blood monitoring equipment, glucose test strips, and related supplies. The

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initial proposal included glucose test strips, lancet, and alcohol wipes. Staff is unaware of industry's reason for expanding the provisions of proposed subdivision (b) to include all patient aids, however, staff continues to believe that statutory authority is lacking to provide an exemption whether it is limited to glucose test strips and lancet or expanded to include all diabetic patient aids.

"Regulation 1591.2, Orthotic Devices"

Other than proposed 1591.2 subdivision (c), the language is basically a restatement of current regulatory language with additional proposed examples based on current annotations. However, industry proposes the following new language in 1591.2 (c)1:

"1. Orthotic devices which qualify as dangerous devices may be dispensed on prescription only by a pharmacist or by a medical device retailer."

As stated in the May 21, 1999 correspondence from Baker & McKenzie,

"In proposed regulation 1591.2, Orthotic Devices, we are concerned with a limitation in subsection (c)(1) which provides that 'Orthotic devices which qualify as dangerous devices may be dispensed on prescription only by a pharmacist or by a medical device retailer.' We are not clear why there is this limitation in the tax code that only pharmacists or medical device retailers may dispense dangerous orthotic devices. We do not view this restriction as necessary in the tax code. Whether such a restriction is necessary in other regulatory schemes is a separate issue. This same comment applies as well to proposed regulation 1591.3(a)(1)."

As discussed previously, staff agrees with this statement. The statutory basis for the sales and use tax exemption, section 6369, does not impose the proposed requirement as a condition to obtaining the exemption. Staff believes Regulation 1591 should not do so either.

In its July 6, 1999 response, industry addresses staff's comments regarding an implied restriction as to the type of entity allowed to furnish orthotic and prosthetic devices. The comments are as follow:

"In the discussion on page 11 of Regulation 1591.2, Orthotic Devices and Regulation 1591.3, Prosthetic Devices, staff questions the inclusion of language relating to the dispensing on prescription only by a pharmacist or medical device retailer. As was responded to earlier, CPhA incorporated this language to indicate that restrictions exist to the sale of such products pursuant to a prescription. It is an attempt to warn persons who might otherwise intend to sell such items that certain restrictions apply. The restriction on the sale of dangerous devices to these two categories of licensees was the specific and explicit intent of the Legislature.

"CPhA is not arguing on behalf of sole dispensing by pharmacists. The Legislature clearly has provided for another source, medical device retailers. The Association's purpose, if you will, would be to prohibit the sales tax exemption to those persons not legally entitled to it, whether or not set forth in Section 6369. If the Board of Equalization wishes to provide a continuing exemption to illegal sales, that is their prerogative."

Staff understands industry's concern, but the proposal has nothing to do with the Sales and Use Tax Law.

"Regulation 1591.3, Prosthetic Devices"

As with proposed subregulation 1591.2, this section provides a restatement of current language with examples based on current annotations. The same restriction discussed in proposed 1591.2 is provided here to limit dispensing of devices to a pharmacist or medical device retailer. The same discussion applies.

FORMAL ISSUE PAPER"Regulation 1591.4, Permanently Implanted Articles"

Industry's proposed subregulation 1591.4 (a) restates existing regulatory language in addition to including new language, as follows:

"(a) Definition

'Permanently implanted articles,' means articles implanted in the human body to assist the functioning, as distinguished from replacing all or any part of any natural organ, artery, vein or limb and which remain or dissolve in the body and whose removal is not otherwise intended."

At this time, staff is not aware of any reason for not including industry's proposed language in the revision of Regulation 1591. The language appears to provide additional clarification for the reader. As such, the information is incorporated in staff's proposed amendment to Regulation 1591.

"Regulation 1591.5, Medical Devices, Supplies and Appliances"

As stated by industry, subregulation 1591.5 includes mostly existing regulatory language, with examples provided based on current annotations. However, when combined with previous proposed subdivisions and subregulations, staff believes the language implies exemptions that may not exist. As with the other provisions of section 6369, the sale of specified devices, supplies, and appliances are considered exempt when meeting specific conditions. It appears that industry's proposal attempts to make the sale of medicines exempt as a class of products. Staff does not agree that is correct under the Sales and Use Tax Law. Medicines are not exempt as a class of products. Rather, the sale of an item, even if qualifying as a medicine, is exempt only if the particular sale of that medicine meets the requirements of the exemption. That is, the sale of medicines is not exempt as a class of products but on a transactional basis.

As stated in industry's July 6, 1999 response:

"CPhA, on the other hand, believes that the users of the Board of Equalization regulations need to know as much as possible, which categories, classes, or types of medical devices, supplies, and appliances are wholly exempt or wholly taxable. Regulations should be designed and written to provide information. CPhA supports the idea that such information should be as specific as possible, with little, if any, room for alternative interpretations."

As stated previously, it is a common misconception that section 6369 exempts a specific class of property. Under section 6369, it is the transaction that is either taxable or exempt.

Proposed subdivision (e) of 1591.5 restates the existing regulatory language regarding wheelchairs, crutches, etc.; however, industry also proposes the addition of "or podiatrist" at the end of the paragraph. As proposed by industry,

"(e)(k) Wheelchairs, Crutches, Canes, Quad Canes and Walkers. Tax does not apply to sales, including leases that are sales, of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, (effective January 1, 1993) and walkers and replacement parts for these devices when sold to the individual for the personal use of that individual as directed by a licensed physician or podiatrist."

Industry states that the proposed language "is added for a prescriber legally authorized to prescribe such items within the scope of his or her practice." Staff believes industry may be referring to a prescriber that is legally authorized under the B&P Code. Sales and Use Tax Law section 6369.2 only mentions "physicians." However, staff does not believe that the Legislature intended to distinguish between the persons authorized to prescribe under section 6369 and the reference to "physicians" in section 6369.2.

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Physicians and podiatrists are authorized pursuant to the B&P Code to prescribe devices, and, in fact, both regularly prescribe wheelchairs, crutches, canes, quad canes, and walkers. Interpreting section 6369.2 to include podiatrists does not appear contrary to the intent of the law. Accordingly, staff has included podiatrist in the proposed amendments to Regulation 1591.

"Regulation 1591.9, Records"

Industry's proposal includes an updated reference to the B&P Code section 4081. Staff has included the update in its proposed amendment to Regulation 1591. Staff does not believe a reference to the powers of the Board under Government Code Section 15618 is necessary.

Discussion - Use of Annotations as Authority

As part of their proposed language, industry has included in each "subregulation" additional examples of items the sales of which they believe qualify for exemption from tax based on applicable annotations. In general, staff agrees that expanded examples would be beneficial in the regulation; however, care must be used to verify that each example is suitable for inclusion in the regulation. It must first be determined that the circumstances considered in the annotation are not so specific that they are not suitable for inclusion in the regulation.

Discussion – Clinical Trial Drugs

Proposed amendments to Regulation 1591 were also submitted by Ernst & Young LLP. They propose subdivision (a) of the current version of Regulation 1591 be amended to add subdivision (a)(8) to provide:

"...Tax does not apply to sales of medicines for the treatment of a human being which medicines are....

"(8) furnished by a pharmaceutical company for the treatment of a human being during any phase of the Food and Drug Administration's drug development and approval process under the supervision of a licensed physician. The exemption provided by the subdivision (a)(8) applies to the constituent elements and ingredients used to produce the medicines, to the tangible personal property which becomes a component part of the drug delivery system, and the material used to package such medicines."

Ernst & Young LLP also proposed to amend the regulation to add subdivision (b)(8) to provide:

"...The term 'Medicines' means and includes....

"(8) drugs furnished by a pharmaceutical company for the treatment of a human being during any phase of the Food and Drug Administration's drug development and approval process under the supervision of a licensed physician."

Sales of substances or preparations that qualify as "medicines" are exempt from sales tax when the sale is pursuant to the provisions of section 6369. This remains true regardless of whether the Food and Drug Administration (FDA) recognizes the substance as a medicine for its purposes. Conversely, even when the FDA declares a substance to be a medicine under its guidelines, the substance may not qualify as a medicine under section 6369.

With regard to the application of the use tax, operative January 1, 1995, the use of medicines furnished by a pharmaceutical company for the treatment of a human being are exempt from the use tax under section 6369, subdivision (a)(6), when such medicines are furnished without charge pursuant to the provisions of that subdivision. However, substances commonly referred to as "placebos" do not qualify as medicines under section 6369. The sale or use of placebos is subject to tax.

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As for the "tangible personal property which becomes a component part of the drug delivery system," staff assumes that the proposal is referring to "pre-filled syringes" or other delivery devices that contain and package the medicines at the time the medicines are provided to the doctor by the pharmaceutical company free of charge. Based on this assumption, the pre-filled syringes and related delivery devices qualify as packaging materials and their use is not taxable as provided in section 6369(a)(6).

Staff agrees in concept with the proposal submitted by Ernst & Young LLP. Information regarding clinical trial drugs is included in staff's proposed amendment to Regulation 1591. However, the actual language and placement differs somewhat from that submitted. Staff's proposed Regulation 1591, subdivision (e)(6), is as follows:

"(4) *Pharmaceutical Manufacturer or Distributor.* Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as Investigational New Drugs by the United States Food and Drug Administration intended for treatment of, and application to, the human body, and which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision (e)(4). Thus, the use of placebos is subject to tax. "

Discussion – Proposed Amendments to Regulation 1591(b)(7) and (b)(8)

On August 6, 1999 staff received a revised proposal from Ernst & Young LLP to amend Regulation 1591(b)(7) and to revise their initially proposed 1591(b)(8). As proposed, subdivision (b)(7) is amended as follows:

"...The term 'Medicines' means and includes....

"(7) Programmable or controlled drug ~~infusion-delivery~~ devices, including those to be worn on, or implanted in, the human body, which ~~automatically~~ cause the ~~infusion-delivery~~ of ~~measured quantities of a~~ medicine into or onto the body of the wearer or user of the device, and the devices that are necessary for the proper placement of such devices into the body or to connect them with the body's tissues."

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The proposal also revises subdivision (b)(8) to provide the following:

"...The term 'Medicines' means and includes....

~~"(8) drugs furnished by a pharmaceutical company for the treatment of a human being during any phase of the Food and Drug Administration's drug development and approval process under the supervision of a licensed physician.~~

"(8) devices that incorporate or contain medicines, and which are necessary to the delivery or use of such medicines into, or onto, the body of a human being in conjunction with the diagnosis, treatment or prevention of disease."

The proposed language was intended to expand the definition of programmable drug infusion devices to include other delivery devices. After further discussions with staff, Ernst & Young LLP agreed to the language provided in staff's proposed Regulation 1591(e)(7) and withdrew their proposed amendments to subdivisions (b)(7) and (b)(8).

V. Staff Recommendation

A. Description of the Staff Recommendation

Staff recommends that Regulation 1591 be amended to reorganize Regulation 1591 into five separate regulations (Exhibit 2 through Exhibit 6) with the incorporation of industry's proposed language and suggestions, when appropriate. Staff also recommends that the reorganization include: 1) information from various annotated legal opinions; 2) clarification that the sale or use of replacement parts for kidney dialysis machines is exempt; 3) clarification that "physician" also includes a podiatrist for the purposes of section 6369.2; and 4) clarification that the use of sample clinical trial drugs is not subject to tax when such samples qualify as medicines, including patches impregnated with medicines. Also, staff does not believe statutory authority exists to amend the regulation to exempt the sale or use of diabetic patient aids.

B. Pros of the Staff Recommendation

- Clarifies the tax application to the sale or use of medicines and other related items.
- Reorganizes the regulation based on statutory authority and subject matter.
- Conceptually incorporates most of industry's amendments and addresses many of their concerns.
- Adheres to what staff believes is the legislative intent of section 6369 and related statutes.
- Consistent with the applicable statutory authority.

C. Cons of the Staff Recommendation

- Does not include all that industry proposed.

D. Statutory or Regulatory Change

Requires a regulatory amendment.

E. Administrative Impact

None expected.

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F. Fiscal Impact

1. Cost Impact

Not applicable.

2. Revenue Impact

Will not result in a revenue impact. See Revenue Estimate.

G. Taxpayer/Customer Impact

Will provide additional clarification for those affected.

H. Critical Time Frames

None.

VI. Alternative 1

A. Description of the Alternative

As proposed by the California Pharmacists Association, amend and reorganize Regulation 1591 in the same manner as described in staff's recommendation; however, the alternative also provides an exemption for the sale or use of diabetic test aids.

B. Pros of the Alternative

- Reorganizes the regulation by subject matter and/or type of substance or device.
- Expands on, and clarifies, various aspects of the regulation.
- Proposes an exemption for the sale or use of diabetic patient aids, resulting in a lower tax reimbursement for consumers of such products.

C. Cons of the Alternative

- Provides an exemption from tax for the sale or use of diabetic patient aids, which staff believes to be contrary to legislative intent.
- Results in a material revenue loss for the State.

D. Statutory or Regulatory Change

Staff believes industry's proposal to exempt the sale or use of diabetic patient aids requires a statutory change. Reorganization requires an amendment to the regulation.

E. Administrative Impact

Minimal impact expected.

F. Fiscal Impact

1. Cost Impact

Not Applicable.

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2. Revenue Impact

The revenue impact of providing an exemption for the sale or use of diabetic patient aids is estimated at \$20.7 million annually. See Revenue Estimate.

G. Taxpayer/Customer Impact

Will provide additional clarification for those affected.

H. Critical Time Frames

None.

Prepared by: Program Planning Division, Sales and Use Tax Department.

Current as of: August 25, 1999.



REGULATION 1591 – MEDICINES AND MEDICAL SUPPLIES, DEVICES AND APPLIANCES

Staff Recommendation

Staff recommends that Regulation 1591 be amended to reorganize Regulation 1591 into five separate regulations (Exhibit 2 through Exhibit 6) with the incorporation of industry's proposed language and suggestions, when appropriate. Staff also recommends that the reorganization include: 1) information from various annotated legal opinions; 2) clarification that the sale or use of replacement parts for kidney dialysis machines is exempt; 3) clarification that "physician" also includes a podiatrist for the purposes of section 6369.2; and 4) clarification that the use of sample clinical trial drugs is not subject to tax when such samples qualify as medicines, including patches impregnated with medicines. Also, staff does not believe statutory authority exists to amend the regulation to exempt the sale or use of diabetic patient aids.

Alternative 1:

As proposed by the California Pharmacists Association, amend and reorganize Regulation 1591 in the same manner as described in staff's recommendation; however, the alternative also provides an exemption for the sale or use of diabetic test aids.

Background, Methodology, and Assumptions

Staff Recommendation:

The staff recommendation would reorganize Regulation 1591 and add language to clarify the taxability of medicines and medical supplies, devices and appliances. The staff recommendation has no revenue effect.

Alternative 1:

Alternative 1 would reorganize Regulation 1591 and would provide an exemption from the sales and use tax for the sale and use of diabetic patient aids. Diabetic patient aids consists of test strips and lancets.

The California Department of Health Services has estimated that there are 1 million diagnosed cases of diabetes in California. Ten percent or 100,000 of these cases are type 1 diabetics. They take daily injections of insulin and they are instructed to use blood glucose monitors. The remaining 90% or 900,000 are type 2 diabetics. Some of these take insulin injections, most do not. A survey taken by the Department of Health Services showed that of those adults surveyed who were diagnosed with

diabetes, 25% were taking insulin. All of those patients that are taking insulin are instructed to monitor their blood glucose. Of the remaining 75%, the Department estimates that half are encouraged to use the monitors. Current medical opinion stresses that regardless of treatment, people who have diabetes need to monitor their disease and use of blood glucose monitors is the only method for doing that.

Monitoring blood glucose requires three items: the blood glucose monitor, test strips and lancets. The patient uses the lancet to draw a small amount of blood. The blood is transferred to the test strip. The test strip is then "read" by the monitor.

The Department of Health Services estimates that patients with type 1 diabetes, who are typically taking multiple injections of insulin daily, monitor their blood glucose 4 times each day. Patients with type 2 diabetes may need multiple injections daily, or need only one injection daily, or may not be taking insulin at all. Those that use monitors may do so 4 times a day, once a day or even once a week. The Department estimates that those type 2 patients that use monitors use them on average 2 times a day.

The major cost to diabetics is for the test strips. Test strips cost 50 to 60 cents each. If a person is using 4 of them each day, he is spending over \$700 a year on test strips. Lancets are a very minor cost for the diabetic. The lancet holder is usually given away with the monitor. The patient needs to purchase only the small needle. Lancets cost \$10 for 200 or 5 cents each.

Sales of test strips:

If all type 1 diabetics are using four strips a day at a cost of 50 cents per strip, sales to these patients would be \$73 million. ($\$0.50 \times 4 \times 365 \times 100,000 = \73 million)

If half of the type 2 diabetics are using 2 strips per day, sales to these patients would be \$164 million. ($\$0.50 \times 2 \times 365 \times 450,000 = \$164,250,000$)

Total annual sales of test strips would be \$237 million (\$73 million + \$164 million)

Sales of lancets:

There are the same number of lancets used as test strips. This amounts to 474,500,000. Lancets cost \$10 for 200 or 5 cents each. Total annual lancet sales therefore are \$24 million. ($474,500,000 \times \$0.05 = \$23,725,000$)

Total sales:

Total sales of test strips and lancets are estimated to be \$261 million (\$237 million + \$24 million = \$261 million). Annually, the state and local sales and use tax revenues on this amount would be \$20.7 million.

Revenue Summary

Staff Recommendation:

The staff recommendation has no revenue effect.

Alternative 1:

The annual revenue impact from exempting the \$261 million in sales of diabetic patient aids from the sales and use tax would be as follows:

<u>Revenue Effect</u>	
State loss (5%)	\$13.1 million
Local loss (2.25%)	5.9 million
Transit loss (0.67%)	1.7 million
Total	\$20.7 million

Preparation

This revenue estimate was prepared by David E. Hayes, Statistics Section, Agency Planning and Research Division. This revenue estimate was reviewed by Ms. Laurie Frost, Chief, Agency Planning and Research Division and Ms. Freda Orendt-Evans, Program Planning Manager, Sales and Use Tax Department. For additional information, please contact Mr. Hayes at (916) 445-0840.

Current as of August 25, 1999

Proposed Revisions to Regulation 1591
Regulations 1591, 1591.1, 1591.2, 1591.3, 1591.4
Current as of 8/25/99

Action Item	Staff's Proposed Regulations 1591, 1591.1, 1591.2, 1591.3, 1591.4	Industry's Proposed Regulatory Language	Summary Comments
Action 1: Consent Item Proposed Regulation 1591, except for subdivision (e)(7).	Proposed Regulation 1591: (a) Definitions. (1) Administer. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means. (2) Dispense. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice. (3) Furnish. "Furnish" means to supply by any means, by sale or otherwise. (4) Health Facility. "Health Facility" as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that: "As used in this chapter 'health facility' means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer...."	Industry's Proposed Regulation 1591: (a) Definitions. (1) Administer. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means. (2) Dispense. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice. (3) Furnish. "Furnish" means to supply by any means, by sale or otherwise. (4) Health Facility. "Health Facility" as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that: "As used in this chapter 'health facility' means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer...."	Staff's Position and Comments: Staff and Industry's language is the same for the proposed amendments to Regulation 1591 except as noted below in subdivision (e)(7).

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	<p>(5) Pharmacist. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of Section 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.</p> <p>(6) Pharmacy. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of Section 4037 of the Business and Professions Code.</p> <p>(7) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p style="padding-left: 40px;">[1.] The name or names and address of</p>	<p>(5) Pharmacist. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of Section 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.</p> <p>(6) Pharmacy. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of Section 4037 of the Business and Professions Code.</p> <p>(7) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p style="padding-left: 40px;">[1.] The name or names and address of</p>	

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	<p>the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(8) Physicians, Dentists, Optometrists, and Podiatrists. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.</p>	<p>the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(8) Physicians, Dentists, Optometrists, and Podiatrists. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.</p>	

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Action Item	Staff's Proposed Regulations 1591, 1591.1, 1591.2, 1591.3, 1591.4	Industry's Proposed Regulatory Language	Summary Comments
	<p>(9) Medicines. "Medicines" means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p> <p>(b) Medicines. The term "medicines" includes the following items:</p> <p>(1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>"Preparations" and similar "substances" include, but are not limited to, drugs such as penicillin and other antibiotics; "dangerous drugs," (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of</p>	<p>(9) Medicines. "Medicines" means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p> <p>(b) Medicines. The term "medicines" includes the following items:</p> <p>(1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>"Preparations" and similar "substances" include, but are not limited to, drugs such as penicillin and other antibiotics; "dangerous drugs," (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of</p>	

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	<p>vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines.</p> <p>(2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not be limited to, permanently implanted artificial sphincters; bone screws and bone pins; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle</p>	<p>vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines.</p> <p>(2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not be limited to, permanently implanted artificial sphincters; bone screws and bone pins; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle</p>	

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	<p>fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheter; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>(4) Orthotic Devices. Orthotic devices, and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p>	<p>fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheter; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>(4) Orthotic Devices. Orthotic devices, and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p>	

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	<p>Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p> <p>Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces.</p>	<p>Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p> <p>Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces.</p>	

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	<p>All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device will not qualify as a medicine for the purposes of this regulation.</p> <p>Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.</p> <p>A "custom-made biomechanical foot orthosis" does not include:</p> <p>(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;</p> <p>(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or</p> <p>(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of</p>	<p>All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device will not qualify as a medicine for the purposes of this regulation.</p> <p>Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.</p> <p>A "custom-made biomechanical foot orthosis" does not include:</p> <p>(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;</p> <p>(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or</p> <p>(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of</p>	

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	<p>manufacture and materials used and regardless of its individual character.</p> <p>(5) Prosthetic Devices. Prosthetic devices and their replacements parts; designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human are medicines as provided under Section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such person, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p> <p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve</p>	<p>manufacture and materials used and regardless of its individual character.</p> <p>(5) Prosthetic Devices. Prosthetic devices and their replacements parts; designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human are medicines as provided under Section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such person, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p> <p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve</p>	

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	<p>stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(6) Drug Infusion Devices. Programmable drug infusion devices worn on or implanted in the human body that automatically cause the infusion of measured quantities of medicine on an intermittent or continuous basis at variable dose rates and at high or low fluid-volume into the body of the wearer of the device qualify as medicines under Section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>(c) Exclusions from the Definition of "Medicines."</p>	<p>stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(6) Drug Infusion Devices. Programmable drug infusion devices worn on or implanted in the human body that automatically cause the infusion of measured quantities of medicine on an intermittent or continuous basis at variable dose rates and at high or low fluid-volume into the body of the wearer of the device qualify as medicines under Section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>(c) Exclusions from the Definition of "Medicines."</p>	

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	<p>Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of_medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.</p> <p>(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.</p> <p>(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).</p>	<p>Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of_medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.</p> <p>(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.</p> <p>(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).</p>	

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	<p>(d) Application of Tax – In General Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:</p> <p>(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or</p> <p>(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or</p> <p>(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or</p> <p>(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or</p> <p>(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or</p>	<p>(d) Application of Tax – In General Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:</p> <p>(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or</p> <p>(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or</p> <p>(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or</p> <p>(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or</p> <p>(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or</p>	

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	<p>(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (d)(6) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.</p> <p>(e) Specific Tax Applications</p> <p>(1) <i>Prescriptions.</i> No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.</p> <p>(2) <i>Licensed Physician, Dentist, or Podiatrist.</i> Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists</p>	<p>(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (d)(6) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.</p> <p>(e) Specific Tax Applications</p> <p>(1) <i>Prescriptions.</i> No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.</p> <p>(2) <i>Licensed Physician, Dentist, or Podiatrist.</i> Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being</p>	

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	<p>or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.</p> <p>(3) <i>Health Facility.</i> Tax does not apply to sales of medicines by a health facility (as defined) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax also does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.</p> <p>(4) <i>Pharmaceutical Manufacturer or Distributor.</i> Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a</p>	<p>regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.</p> <p>(3) <i>Health Facility.</i> Tax does not apply to sales of medicines by a health facility (as defined) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax also does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.</p> <p>(4) <i>Pharmaceutical Manufacturer or Distributor.</i> Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state.</p>	

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	<p>resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.</p> <p>This exemption applies in the same manner to the use of clinical trial medicines during the Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as Investigational New Drugs by the United States Food and Drug Administration intended for treatment of, and application to, the human body, and which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision (e)(4). Thus, the use of placebos is subject to tax.</p> <p>(5) <i>Antimicrobial Agents Used by Hospital</i></p>	<p>When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.</p> <p>This exemption applies in the same manner to the use of clinical trial medicines during the Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as Investigational New Drugs by the United States Food and Drug Administration intended for treatment of, and application to, the human body, and which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision (e)(4). Thus, the use of placebos is subject to tax.</p> <p>(5) <i>Antimicrobial Agents Used by Hospital Personnel.</i> Tax does not apply to the sale or use of</p>	

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	<p><i>Personnel.</i> Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and, as such, the sale or use of these products is subject to tax.</p> <p>(6) <i>Vitamins, Minerals, Herbs, and Other Such Supplements.</i> In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of</p>	<p>substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and, as such, the sale or use of these products is subject to tax.</p> <p>(6) <i>Vitamins, Minerals, Herbs, and Other Such Supplements.</i> In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p>	

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Action Item #2: Staff's Proposed Regulation 1591(e)(7) or Industry's proposed Regulation 1591(e)(7)	<p>the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>(7) <i>Diagnostic Substances, Test Kits, and Equipment.</i> Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment, they are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines for the purposes of the exemption provided under Section 6369.</p> <p>Tax also applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether or not they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.</p> <p>(f) Insurance Payments</p> <p>(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not</p>	<p>(7) <i>Diagnostic Substances, Test Kits, and Equipment.</i> Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment, they are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines for the purposes of the exemption provided under Section 6369.</p> <p>Except as otherwise provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether or not they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.</p> <p>(f) Insurance Payments</p> <p>(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in</p>	<p>Industry's proposed language provides an exemption for glucose test strips and skin puncture lancets. Staff's proposal does not provide this exemption. Staff believes industry's proposal lacks statutory authority.</p>

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	<p>affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.</p> <p>(2) Medicare</p> <p>(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the U.S. Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the U.S. Government.</p> <p>(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the U.S. Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as an exempt sale of a medicine), the sale is subject to tax.</p>	<p>whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.</p> <p>(2) Medicare</p> <p>(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the U.S. Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the U.S. Government.</p> <p>(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the U.S. Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as an exempt sale of a medicine), the sale is subject to tax.</p> <p>(3) Employer Medical Contracts. Certain employers have contracted with their employees to</p>	

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	<p>(3) Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to outpatients but not to in-patients. This in no way affects the exemption of sales of medicines.</p> <p>(g) Records. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.</p> <p>Pursuant to Section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.</p> <p>(1) The following written information constitutes acceptable documentation for retailers in those</p>	<p>provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to outpatients but not to in-patients. This in no way affects the exemption of sales of medicines.</p> <p>(g) Records. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.</p> <p>Pursuant to Section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.</p> <p>(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within</p>	

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Action 1: Consent Item Staff's Regulation 1591.1, except subdivision (b)(4)	<p>cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Section 6369:</p> <p style="padding-left: 40px;">Name of purchaser Name of doctor Date of sale Item sold The sale price</p> <p>(2) "Double Deduction" Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.</p> <p>(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.</p> <p>Proposed Regulation 1591.1, Specific Medical Devices, Appliances, and Related Supplies:</p> <p>(a) Definitions.</p> <p>(1) Physicians, Dentists, Optometrists, and Podiatrists. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's</p>	<p>the meaning of Section 6369:</p> <p style="padding-left: 40px;">Name of purchaser Name of doctor Date of sale Item sold The sale price</p> <p>(2) "Double Deduction" Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.</p> <p>(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.</p> <p>Proposed Regulation 1591.1, Specific Medical Devices, Appliances, and Related Supplies:</p> <p>(a) Definitions.</p> <p>(1) Physicians, Dentists, Optometrists, and Podiatrists. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California</p>	<p>Staff and industry's language is the same except for subdivision (b)(4).</p>

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	<p>certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.</p> <p>(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p>[1.] The name or names and address of the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p>	<p>or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.</p> <p>(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p>[1.] The name or names and address of the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(b) Specific Applications.</p>	

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	<p>(b) Specific Applications.</p> <p>(1) Hemodialysis Products. Tax does not apply to the sale or use of hemodialysis products supplied on order of a licensed physician and surgeon to a patient by a pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to the patient.</p> <p>(2) Mammary Prostheses and Ostomy Appliances and Related Supplies. Tax does not apply to the sale or use of mammary prostheses and ostomy appliances and related supplies required as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste when sold or furnished under one of the conditions provided in Regulation 1591 subdivision (d)(1) through (d)(6). The mammary prostheses devices and ostomy appliances and related supplies do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as they are furnished pursuant to a written order of a person authorized to prescribe.</p> <p>Ostomy appliances and related supplies must be used in postoperative situations or sold as an accommodation to patients following surgery in order to qualify as medicines. When used as an adjunct to surgical procedures, the sale or use of</p>	<p>(1) Hemodialysis Products. Tax does not apply to the sale or use of hemodialysis products supplied on order of a licensed physician and surgeon to a patient by a pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to the patient.</p> <p>(2) Mammary Prostheses and Ostomy Appliances and Related Supplies. Tax does not apply to the sale or use of mammary prostheses and ostomy appliances and related supplies required as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste when sold or furnished under one of the conditions provided in Regulation 1591 subdivision (d)(1) through (d)(6). The mammary prostheses devices and ostomy appliances and related supplies do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as they are furnished pursuant to a written order of a person authorized to prescribe.</p> <p>Ostomy appliances and related supplies must be used in postoperative situations or sold as an accommodation to patients following surgery in order to qualify as medicines. When used as an adjunct to surgical procedures, the sale or use of these items is subject to tax unless the appliances remain in the patient for postoperative purposes.</p>	

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	<p>these items is subject to tax unless the appliances remain in the patient for postoperative purposes. Qualifying mammary prostheses and qualifying ostomy appliances and related supplies include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover; catheters used as a result of an artificial opening created in the human body; colostomy bags; deodorant used on the person of the user; karaya rings; antacid used externally as a skin ointment; skin gel; nonallergic paper tape and gauze; skin bond cement; tincture of benzoin applied topically as a protective; urinary drainage appliances; closed stoma bags; drainable stoma bags; loop ostomy supplies and tubing; and endotracheal and tracheotomy tubes used for the evacuation of metabolic waste when used post-operatively or for home care. Tracheostomy tubes used to facilitate the passage of air do not qualify as medicines for the purposes of Section 6369.</p> <p><i>Kidney Dialysis Machines.</i> The term “ostomy appliances” and “related supplies” includes kidney dialysis machines, replacement parts for the kidney dialysis machines, and the catheters, dialysis fluid additives, volumetric infusion pumps, tubing, blood sets, fistula sets, and shunts used in conjunction with such machines. In order to qualify as a “related supply,” an item must be a necessary and integral part of the machine itself, or a substance or preparation intended for external or internal application to the human body of the patient</p>	<p>Qualifying mammary prostheses and qualifying ostomy appliances and related supplies include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover; catheters used as a result of an artificial opening created in the human body; colostomy bags; deodorant used on the person of the user; karaya rings; antacid used externally as a skin ointment; skin gel; nonallergic paper tape and gauze; skin bond cement; tincture of benzoin applied topically as a protective; urinary drainage appliances; closed stoma bags; drainable stoma bags; loop ostomy supplies and tubing; and endotracheal and tracheotomy tubes used for the evacuation of metabolic waste when used post-operatively or for home care. Tracheostomy tubes used to facilitate the passage of air do not qualify as medicines for the purposes of Section 6369.</p> <p><i>Kidney Dialysis Machines.</i> The term “ostomy appliances” and “related supplies” includes kidney dialysis machines, replacement parts for the kidney dialysis machines, and the catheters, dialysis fluid additives, volumetric infusion pumps, tubing, blood sets, fistula sets, and shunts used in conjunction with such machines. In order to qualify as a “related supply,” an item must be a necessary and integral part of the machine itself, or a substance or preparation intended for external or internal application to the human body of the patient undergoing dialysis.</p>	

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	<p>undergoing dialysis.</p> <p>(3) Catheters. Generally, sales of catheters are subject to tax in the same manner as other sales of tangible personal property. However, sales of the following types of catheters are not subject to tax.</p> <p>(A) Intra-aortic balloon pump catheters and coronary angioplasty balloon catheters.</p> <p>However, sales of related supplies are subject to tax. The term "related supplies" includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, homeostatic valves, inflation devices, and syringes.</p> <p>(B) Catheters which are permanently implanted in the human body and assist the functioning of a natural organ, artery, vein, or limb and remain or dissolve in the body.</p> <p>(C) Catheters used for drainage purposes through which an artificial opening is created in the human body. Such catheters qualify as ostomy materials and related supplies.</p> <p>(D) Catheters or similar types of devices used for drainage purposes through natural openings in the human body to assist or replace the functioning of a natural part of the human body. Such catheters are designed to be worn on or in the body of the user and qualify as prosthetic devices.</p> <p>(4) Insulin and Insulin Syringes. "Insulin" and "insulin syringes" furnished by a pharmacist to a</p>	<p>(3) Catheters. Generally, sales of catheters are subject to tax in the same manner as other sales of tangible personal property. However, sales of the following types of catheters are not subject to tax.</p> <p>(A) Intra-aortic balloon pump catheters and coronary angioplasty balloon catheters.</p> <p>However, sales of related supplies are subject to tax. The term "related supplies" includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, homeostatic valves, inflation devices, and syringes.</p> <p>(B) Catheters which are permanently implanted in the human body and assist the functioning of a natural organ, artery, vein, or limb and remain or dissolve in the body.</p> <p>(C) Catheters used for drainage purposes through which an artificial opening is created in the human body. Such catheters qualify as ostomy materials and related supplies.</p> <p>(D) Catheters or similar types of devices used for drainage purposes through natural openings in the human body to assist or replace the functioning of a natural part of the human body. Such catheters are designed to be worn on or in the body of the user and qualify as prosthetic devices.</p> <p>(4) Insulin and Insulin Syringes. "Insulin" and "insulin syringes" furnished by a pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on</p>	

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<p>Action Item #2: Staff's Regulation 1591.1(b)(4) or Industry's Proposed Regulation 1591.1(b)(4)</p> <p>Action 1: Consent Item Proposed Regulation 1591.2</p>	<p>person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369(e). As such, the sale or use of insulin and insulin syringes furnished by a pharmacist to a person for treatment of diabetes, as directed by a physician, is exempt from tax.</p> <p>However, the exemption provided under Section 6369(e) does not apply to the sale or use of glucose monitoring systems. Blood glucose monitors, glucose test strips, lancets, and other related items are used by a patient to monitor and test his or her blood sugar level, they are not applied to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease. Since the system and related items do not qualify as medicines or come under the exemption provided by Section 6369(e), their sale or use is subject to tax regardless of whether or not they are furnished pursuant to the direction of a licensed physician.</p> <p>Proposed Regulation 1591.2 Wheelchairs, Crutches, Canes, and Walkers. (a) Definitions. (1) Physician. For purposes of this regulation, "physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California, the Osteopathic Medical Board of</p>	<p>prescription within the meaning of Section 6369(e). As such, the sale or use of insulin and insulin syringes furnished by a pharmacist to a person for treatment of diabetes, as directed by a physician, is exempt from tax.</p> <p>Glucose test strips and skin puncture lancets furnished by a registered pharmacist that are used by a diabetic patient to determine his or her own blood sugar level and the necessity for and amount of insulin and/or other diabetic control medication needed to treat the disease in accordance with a physician's instructions are an integral and necessary active part of the use of insulin and insulin syringes or other anti-diabetic medications and, accordingly, are not subject to sale or use tax pursuant to subsection (e) of Section 6369. These medical supplies are not medicines and do not qualify for sales or use tax exemption under subsections (a) or (b) of Section 6369.</p> <p>Proposed Regulation 1591.2 Wheelchairs, Crutches, Canes, and Walkers. (a) Definitions. (1) Physician. For purposes of this regulation, "physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. Physician, as defined, includes doctors of medicines (MD),</p>	<p>Industry's second paragraph expands the definition of medicines to include glucose test strips and lancets that are believed by staff to be specifically excluded from the definition of medicines. Staff does not believe that the Legislature intended to include test strips and lancets in the exemption provided under Section 6369(e) when enacting the legislation. As such, staff believes the proposal lacks statutory authority.</p> <p>Staff and industry's language is the same.</p>

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	<p>California, or the California Board of Podiatric Medicine. Physician, as defined, includes doctors of medicines (MD), doctors of osteopathy (DO), and doctors of podiatric medicine (DPM).</p> <p>(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p>[1.] The name or names and address of the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(3) Health Facility. "Health Facility" as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which</p>	<p>doctors of osteopathy (DO), and doctors of podiatric medicine (DPM).</p> <p>(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p>[1.] The name or names and address of the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(3) Health Facility. "Health Facility" as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:</p> <p>"As used in this chapter 'health facility'</p>	

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	<p>provides that:</p> <p>“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”</p> <p>(b) Tax Application. Tax does not apply to the sale or use, including leases that are continuing sales and purchases, of wheelchairs; crutches; canes; quad canes; white canes used by the legally blind; walkers; and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician. Electric three-wheel scooters that are similar in both design and function to a conventional electric wheelchair, qualify as a wheelchair for the purposes of Section 6369.2. When the scooters are sold or leased to an individual for the personal use of that individual as directed by a licensed physician their sale or use qualifies for an exemption from tax.</p> <p>“Replacement parts” include, but are not limited to, batteries for electric wheelchairs; belts and cushions sold to replace or supplement the basic items originally sold with wheelchairs, lap boards</p>	<p>means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”</p> <p>(b) Tax Application. Tax does not apply to the sale or use, including leases that are continuing sales and purchases, of wheelchairs; crutches; canes; quad canes; white canes used by the legally blind; walkers; and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician. Electric three-wheel scooters that are similar in both design and function to a conventional electric wheelchair, qualify as a wheelchair for the purposes of Section 6369.2. When the scooters are sold or leased to an individual for the personal use of that individual as directed by a licensed physician their sale or use qualifies for an exemption from tax.</p> <p>“Replacement parts” include, but are not limited to, batteries for electric wheelchairs; belts and cushions sold to replace or supplement the basic items originally sold with wheelchairs, lap boards and trays attached to wheelchairs and considered a part of the wheelchair; and rubber tips, wheels, and</p>	

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	<p>and trays attached to wheelchairs and considered a part of the wheelchair; and rubber tips, wheels, and other such items prescribed for an individual to replace an original component of the device sold. "Replacement parts" do not include items such as mechanical devices that aid the patient in eating or writing unless the items are part of the device itself, or restraints or other such items sold to an individual, but which do not become a part of the wheelchair or other such prescribed device.</p> <p>(c) Sales to Health Facilities. Sales, or leases that are continuing sales and purchases, of wheelchairs, crutches, canes, and walkers to hospitals or other health facilities for use by patients while at the facilities are subject to tax. Such sales or leases are not considered sold to an individual for the individual's personal use as directed by a physician. However, when wheelchairs, crutches, canes, and walkers are ordered by a hospital or health facility on behalf of a specific patient, as directed by a physician, the items may be considered to be purchased by an individual for his or her own personal use as required under Section 6369.2 and, therefore, the sale will qualify for exemption from tax.</p> <p>(d) Sales to Insured Persons. The exemption for qualifying retail sales of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, walkers, and replacement parts for these devices is not affected by the fact that charges to</p>	<p>other such items prescribed for an individual to replace an original component of the device sold. "Replacement parts" do not include items such as mechanical devices that aid the patient in eating or writing unless the items are part of the device itself, or restraints or other such items sold to an individual, but which do not become a part of the wheelchair or other such prescribed device.</p> <p>(c) Sales to Health Facilities. Sales, or leases that are continuing sales and purchases, of wheelchairs, crutches, canes, and walkers to hospitals or other health facilities for use by patients while at the facilities are subject to tax. Such sales or leases are not considered sold to an individual for the individual's personal use as directed by a physician. However, when wheelchairs, crutches, canes, and walkers are ordered by a hospital or health facility on behalf of a specific patient, as directed by a physician, the items may be considered to be purchased by an individual for his or her own personal use as required under Section 6369.2 and, therefore, the sale will qualify for exemption from tax.</p> <p>(d) Sales to Insured Persons. The exemption for qualifying retail sales of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, walkers, and replacement parts for these devices is not affected by the fact that charges to the individual to whom such items are sold, may be paid, in whole or in part, by an insurer. This is so</p>	

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Action 1: Consent Item Proposed Regulation 1591.3	<p>the individual to whom such items are sold, may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.</p> <p>Regulation 1591.3 Vehicles for Physically Handicapped Persons.</p> <p>(a) Definitions.</p> <p>(1) Physically Handicapped Persons. For purposes of this regulation, "physically handicapped" persons include disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.</p> <p>(2) Vehicle. For purposes of this regulation, "vehicle" includes all devices that qualify under Vehicle Code Section 670 as "vehicles" including, but not limited to, automobiles, vans, trucks, mobilehomes and trailercoaches. "Vehicles" qualifying under this regulation mean and include:</p> <p>(A) Vehicles which are owned and operated by physically handicapped persons and,</p> <p>(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.</p>	<p>even though a joint billing may be made by the retailer in the name of both the person and the insurer.</p> <p>Regulation 1591.3 Vehicles for Physically Handicapped Persons.</p> <p>(a) Definitions.</p> <p>(1) Physically Handicapped Persons. For purposes of this regulation, "physically handicapped" persons include disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.</p> <p>(2) Vehicle. For purposes of this regulation, "vehicle" includes all devices that qualify under Vehicle Code Section 670 as "vehicles" including, but not limited to, automobiles, vans, trucks, mobilehomes and trailercoaches. "Vehicles" qualifying under this regulation mean and include:</p> <p>(A) Vehicles which are owned and operated by physically handicapped persons and,</p> <p>(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.</p> <p>(b) Application of Tax. Tax does not apply to the sale or use of items and materials used to modify a</p>	<p>Staff and Industry's language is the same.</p>

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	<p>(b) Application of Tax. Tax does not apply to the sale or use of items and materials used to modify a vehicle for physically handicapped persons when such items are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. However, sales or purchases of tools and supplies used in modifying the vehicle and which are not incorporated into, attached to, or installed on the vehicle are subject to tax.</p> <p>Items and materials considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an interlock system; upper torso restraint; an airbag of a unique type to raise or lower the vehicle for loading or unloading; running boards on lower side of vehicle; a bolt cam used to restrain a wheelchair inside a van; seat belts; a tire carrier to hold a spare and which is installed within reach of a handicapped person; AC lights to illuminate the ramp or elevator area; hardware for privacy curtains; air compressor for use with medical equipment; a 12-volt receptacle to supply power to medical equipment; a 4-point tie down system to restrain a wheelchair; and an allocable portion(s) of the various interior packages, interior materials, and conversions necessary to modify the vehicle for transport of physically handicapped persons.</p>	<p>vehicle for physically handicapped persons when such items are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. However, sales or purchases of tools and supplies used in modifying the vehicle and which are not incorporated into, attached to, or installed on the vehicle are subject to tax.</p> <p>Items and materials considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an interlock system; upper torso restraint; an airbag of a unique type to raise or lower the vehicle for loading or unloading; running boards on lower side of vehicle; a bolt cam used to restrain a wheelchair inside a van; seat belts; a tire carrier to hold a spare and which is installed within reach of a handicapped person; AC lights to illuminate the ramp or elevator area; hardware for privacy curtains; air compressor for use with medical equipment; a 12-volt receptacle to supply power to medical equipment; a 4-point tie down system to restrain a wheelchair; and an allocable portion(s) of the various interior packages, interior materials, and conversions necessary to modify the vehicle for transport of physically handicapped persons.</p> <p>Items and materials that are generally not considered necessary to enable a vehicle to be used</p>	

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	<p>Items and materials that are generally not considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an upper torso durable pad (unless part of the restraint); portable ramps (telescopic); air conditioners (unless necessary for the transport of certain types of disabled persons); a fire extinguisher; a CB radio (unless shown to be necessary to the transport of certain types of disabled persons); leather seat covers; extra windows and their accessories; upgrades to the interior (upgrade to leather seats); and an engine cover. The sale or use of such items, whether installed on a vehicle to be used for transport of physically handicapped persons or not, are generally subject to tax.</p> <p>(c) Sales of Modified Vehicles. Tax does not apply to the gross receipts attributable to the portion of a vehicle that has been modified to enable the vehicle to be used to transport a physically handicapped person or persons when the modified vehicle is sold to a physically handicapped person, as defined.</p> <p>(d) Repairs to Modified Vehicles. Tax does not apply to the sale or use of items and materials used to repair the modified portion (the portion that contains equipment previously used to modify the vehicle) of a vehicle used to transport a physically handicapped person or persons. Once installed, such "repair parts" qualify as items and materials used to modify a vehicle in order for the vehicle to</p>	<p>to transport a physically handicapped person include, but are not limited to, an upper torso durable pad (unless part of the restraint); portable ramps (telescopic); air conditioners (unless necessary for the transport of certain types of disabled persons); a fire extinguisher; a CB radio (unless shown to be necessary to the transport of certain types of disabled persons); leather seat covers; extra windows and their accessories; upgrades to the interior (upgrade to leather seats); and an engine cover. The sale or use of such items, whether installed on a vehicle to be used for transport of physically handicapped persons or not, are generally subject to tax.</p> <p>(c) Sales of Modified Vehicles. Tax does not apply to the gross receipts attributable to the portion of a vehicle that has been modified to enable the vehicle to be used to transport a physically handicapped person or persons when the modified vehicle is sold to a physically handicapped person, as defined.</p> <p>(d) Repairs to Modified Vehicles. Tax does not apply to the sale or use of items and materials used to repair the modified portion (the portion that contains equipment previously used to modify the vehicle) of a vehicle used to transport a physically handicapped person or persons. Once installed, such "repair parts" qualify as items and materials used to modify a vehicle in order for the vehicle to be used to transport a physically handicapped person or persons.</p>	

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Action 1: Consent Item Proposed Regulation 1591.4	<p>be used to transport a physically handicapped person or persons.</p> <p>Proposed Regulation 1591.4 Medical Oxygen Delivery Systems.</p> <p>(a) Definitions.</p> <p>(1) Physician. "Physicians" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.</p> <p>(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p>[1.] The name or names and address of the patient or patients.</p> <p>[2.] The name and quantity of the drug or</p>	<p>Proposed Regulation 1591.4 Medical Oxygen Delivery Systems.</p> <p>(a) Definitions.</p> <p>(1) Physician. "Physicians" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.</p> <p>(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state <i>and</i> given individually for the person or persons for whom ordered. The order must include all of the following:</p> <p>[1.] The name or names and address of the patient or patients.</p> <p>[2.] The name and quantity of the drug or device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p>	<p>Staff and Industry's language is the same.</p>

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	<p>device prescribed and the directions for use.</p> <p>[3.] The date of issue.</p> <p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(3) Health Facility. "Health Facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.</p> <p>(4) Medical Oxygen Delivery System. A system used to administer oxygen directly into the lungs of the patient for the relief of conditions in which the human body experiences an abnormal deficiency or inadequate supply of oxygen. Devices that only assist the patient in breathing, but do not deliver air or oxygen directly into the lungs of the patient, do</p>	<p>[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.</p> <p>[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>[6.] If in writing, signed by the prescriber issuing the order.</p> <p>(3) Health Facility. "Health Facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.</p> <p>(4) Medical Oxygen Delivery System. A system used to administer oxygen directly into the lungs of the patient for the relief of conditions in which the human body experiences an abnormal deficiency or inadequate supply of oxygen. Devices that only assist the patient in breathing, but do not deliver air or oxygen directly into the lungs of the patient, do not qualify as medical oxygen delivery systems.</p>	

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	<p>not qualify as medical oxygen delivery systems.</p> <p>(b) Tax Application.</p> <p>(1) Medical Oxygen Delivery Systems. Tax does not apply to the sale or use of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. Medical oxygen delivery systems include, but are not limited to, liquid oxygen containers, high-pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the patient. The term also includes repair and replacement parts for use in such a system.</p> <p>(2) Ventilators and Other Respiratory Equipment. For the purposes of this regulation, ventilators that produce a form of controlled respiration in which compressed air is delivered under positive pressure into the patient's airways qualify for the exemption provided under Section 6369.5 for medical oxygen delivery systems. Pressure ventilators and volume ventilators provide assisted respiration and intensive positive pressure in which compressed air, a component of which is oxygen, is administered into the breathing systems of patients to help them breathe. The sale or use of ventilators, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician</p> <p>Respiratory equipment that induces air into the</p>	<p>(b) Tax Application.</p> <p>(1) Medical Oxygen Delivery Systems. Tax does not apply to the sale or use of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. Medical oxygen delivery systems include, but are not limited to, liquid oxygen containers, high-pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the patient. The term also includes repair and replacement parts for use in such a system.</p> <p>(2) Ventilators and Other Respiratory Equipment. For the purposes of this regulation, ventilators that produce a form of controlled respiration in which compressed air is delivered under positive pressure into the patient's airways qualify for the exemption provided under Section 6369.5 for medical oxygen delivery systems. Pressure ventilators and volume ventilators provide assisted respiration and intensive positive pressure in which compressed air, a component of which is oxygen, is administered into the breathing systems of patients to help them breathe. The sale or use of ventilators, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician</p> <p>Respiratory equipment that induces air into the lungs of a patient, through the application of pressure to the chest area, also qualifies for the</p>	

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	<p>lungs of a patient, through the application of pressure to the chest area, also qualifies for the exemption provided for medical oxygen delivery systems, regardless of whether the pressure applied is negative pressure or positive pressure. The sale or use of respiratory equipment, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician. Included within the scope of the exemption are exsufflation belts, iron lungs, chest shells, pulmo wraps, and the pumps and regulators necessary for the operation of the listed equipment.</p> <p>(c) Sales to Health Facilities and Health Care Providers. Sales of medical oxygen delivery systems are exempt when sold to an individual for his or her own use under the direction of a licensed physician. Sales of medical oxygen delivery systems to hospitals, immediate care facilities, physicians, or other health care providers for use on their premises are subject to tax in the same manner as other sales of tangible personal property.</p> <p>A rental or lease of a medical oxygen delivery system to a health facility qualifies for an exemption from tax when the facility intends to lease or rent the system to an individual for the personal use of that individual as directed by a licensed physician and the system is then leased or rented as intended. However, the transaction between the health facility and the individual must</p>	<p>exemption provided for medical oxygen delivery systems, regardless of whether the pressure applied is negative pressure or positive pressure. The sale or use of respiratory equipment, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician. Included within the scope of the exemption are exsufflation belts, iron lungs, chest shells, pulmo wraps, and the pumps and regulators necessary for the operation of the listed equipment.</p> <p>(c) Sales to Health Facilities and Health Care Providers. Sales of medical oxygen delivery systems are exempt when sold to an individual for his or her own use under the direction of a licensed physician. Sales of medical oxygen delivery systems to hospitals, immediate care facilities, physicians, or other health care providers for use on their premises are subject to tax in the same manner as other sales of tangible personal property.</p> <p>A rental or lease of a medical oxygen delivery system to a health facility qualifies for an exemption from tax when the facility intends to lease or rent the system to an individual for the personal use of that individual as directed by a licensed physician and the system is then leased or rented as intended. However, the transaction between the health facility and the individual must constitute an actual lease or rental. When the patient's use of the medical delivery system is</p>	

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	<p>constitute an actual lease or rental. When the patient's use of the medical delivery system is limited to the health facility's premises, the direction and control of the equipment does not transfer to the patient. Therefore, an actual lease or rental of the system to the patient does not occur even when a separate billing is made to the patient for the use of the system. As such, the lease or rental of the system to the health facility does not qualify for the exemption provided under Section 6369.5.</p> <p>(d) Sales of Medical Oxygen. Medical oxygen and other gases sold to a licensed physician and surgeon, podiatrist, dentist, or health facility for treatment of human beings are considered medicines. Therefore, their sale or use is not subject to tax when (1) furnished by a licensed physician and surgeon, podiatrist, or dentist to his or her own patient or (2) furnished by the health facility pursuant to the order of a licensed physician and surgeon, dentist, or podiatrist.</p> <p>Medical oxygen sold by distributors of compressed gases to an individual for use as part of the individual's treatment, pursuant to a physician's prescription, is regarded as a medicine furnished by a licensed physician to his or her own patient for treatment of the patient as provided by Regulation 1591(b)(2). Sales of medical oxygen to individuals under the "Casey Bill" (i.e., the retailer bills the service acting as a fiscal agent for the State of</p>	<p>limited to the health facility's premises, the direction and control of the equipment does not transfer to the patient. Therefore, an actual lease or rental of the system to the patient does not occur even when a separate billing is made to the patient for the use of the system. As such, the lease or rental of the system to the health facility does not qualify for the exemption provided under Section 6369.5.</p> <p>(d) Sales of Medical Oxygen. Medical oxygen and other gases sold to a licensed physician and surgeon, podiatrist, dentist, or health facility for treatment of human beings are considered medicines. Therefore, their sale or use is not subject to tax when (1) furnished by a licensed physician and surgeon, podiatrist, or dentist to his or her own patient or (2) furnished by the health facility pursuant to the order of a licensed physician and surgeon, dentist, or podiatrist.</p> <p>Medical oxygen sold by distributors of compressed gases to an individual for use as part of the individual's treatment, pursuant to a physician's prescription, is regarded as a medicine furnished by a licensed physician to his or her own patient for treatment of the patient as provided by Regulation 1591(b)(2). Sales of medical oxygen to individuals under the "Casey Bill" (i.e., the retailer bills the service acting as a fiscal agent for the State of California) are regarded as sales of medicines to this State for use in the treatment of human beings</p>	

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	<p>California) are regarded as sales of medicines to this State for use in the treatment of human beings as provided by Regulation 1591(b)(5). Therefore, sales of medical oxygen by such distributors, under these conditions, are not subject to tax whether or not the distributor is a medical supply house.</p> <p>(e) Sales to Insured Persons. The exemption for qualifying retail sales of oxygen delivery systems and replacement parts is not affected by the fact that charges to the individual for whom such items are sold, leased, or rented may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.</p>	<p>as provided by Regulation 1591(b)(5). Therefore, sales of medical oxygen by such distributors, under these conditions, are not subject to tax whether or not the distributor is a medical supply house.</p> <p>(e) Sales to Insured Persons. The exemption for qualifying retail sales of oxygen delivery systems and replacement parts is not affected by the fact that charges to the individual for whom such items are sold, leased, or rented may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.</p>	

REGULATION 1591. MEDICINES AND MEDICAL Supplies, DEVICES and Appliances

Reference: Sections 6006 and 6369, ~~6369.1, 6369.2, 6369.4 and 6369.5~~ Revenue and Taxation Code.

~~(a) General. Tax applies to retail sales of drugs, medicines, and other tangible personal property by pharmacists and others except as follows:~~

~~Tax does not apply to sales of medicines for the treatment of a human being which medicines are:~~

~~—(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law, or~~

~~—(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or~~

~~—(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or~~

~~—(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or~~

~~—(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or~~

~~—(6) hemodialysis products supplied on order of a licensed physician to a patient by a registered pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to a hemodialysis patient, or~~

~~—(7) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (a)(7) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.~~

(a) Definitions.

(1) Administer. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) Dispense. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of

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drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.

(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”

(5) Pharmacist. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of Section 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”

(6) Pharmacy. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of Section 4037 of the Business and Professions Code.

(7) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(8) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and

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includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(9) Medicines. "Medicines" means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) Definition of "Medicines." Medicines. The term "medicines" includes the following items:

(1) ~~any~~ Preparations and Similar Substances. Preparations and similar substances or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which ~~is~~are commonly recognized as a substance or preparation intended for such use; qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations" and similar "substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines.

(2) Permanently Implanted Articles. ~~Bone screws, bone pins, pacemakers, and other~~ Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. ~~The term also includes sutures, whether or not permanently implanted. A nonreturnable, nonreusable needle fused or prethreaded to a suture is regarded as a part of the suture.~~ An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not be limited to, permanently implanted artificial sphincters; bone screws and bone pins; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheter; temporary myocardial pacing leads used during surgery

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and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.

(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) Orthotic Devices. Orthotic devices, ~~and or their replacement parts~~, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure; ~~provided, that orthopedic shoes and supportive devices for the foot are not exempt unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses.~~ are medicines as provided under Section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

~~“Custom-made biomechanical foot orthosis” means a device which is made on a positive model of the individual patient’s foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology. The device described above excludes~~

- ~~—(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;~~
- ~~—(B) any foot orthosis fabricated directly on the patient’s foot regardless of the method and materials used and regardless of its individual character; and~~
- ~~—(C) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of manufacture and materials used and regardless of its individual character.~~

“Orthotic devices” worn on the body of the person includes, but ~~are~~ is not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device will not qualify as a medicine for the purposes of this regulation.

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Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient’s foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

A “custom-made biomechanical foot orthosis” does not include:

- (A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;
- (B) any foot orthosis fabricated directly on the patient’s foot regardless of the method and materials used and regardless of its individual character; or
- (C) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) Prosthetic Devices. Prosthetic devices ~~or~~ and their replacements parts; designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body ~~other than auditory, ophthalmic and ocular devices or appliances, and other than dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth and other dental prosthetic materials and devices.~~ are medicines as provided under Section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such person, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

~~(6) Artificial eyes, or their replacement parts, intraocular lenses for human beings, and ear implants.~~

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(76) Drug Infusion Devices. Programmable drug infusion devices worn on or implanted in the human body that automatically cause the infusion of measured quantities of medicine on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) Exclusions from ~~Term~~ the Definition of “Medicines.”

Except as otherwise provided in ~~(b)(2) through (b)(7) above,~~ subdivision (b), the following items are specifically excluded from the term definition of medicines:. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).

~~(d) Who is a “Registered Pharmacist”. A “registered pharmacist” is defined under Section 4036 of the Business and Professions Code as follows:~~

~~“‘Pharmacist’ means a person to whom a license has been issued by the board, under the provisions of Section 4200, except as specifically provided otherwise in this chapter.”~~

(d) Application of Tax – In General

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law,
or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (d)(6) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

~~(e) What Constitutes a "Prescription." Section 4040 of the Business and Professions Code defines "prescription" as follows:~~

~~"'Prescription' means an oral, written, or electronic transmission order that is both of the following: (1) Given individually for the person or persons for whom ordered that includes all of the following: (A) The name or names and address of the patient or patients. (B) The name and quantity of the drug or device prescribed and the directions for use. (C) The date of issue. (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed. (E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients. (F) If in writing, signed by the prescriber issuing the order. (2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian licensed in this state."~~

~~No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being.~~

(e) Specific Tax Applications

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

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(2) *Licensed Physician, Dentist, or Podiatrist.* Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) *Health Facility.* Tax does not apply to sales of medicines by a health facility (as defined) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax also does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) *Pharmaceutical Manufacturer or Distributor.* Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration’s drug development and approval process. “Clinical trial medicines” are substances or preparations approved as Investigational New Drugs by the United States Food and Drug Administration intended for treatment of, and application to, the human body, and which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision (e)(4). Thus, the use of placebos is subject to tax.

(5) *Antimicrobial Agents Used by Hospital Personnel.* Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient’s treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the

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body of hospital personnel are not considered used in the treatment of the patient and, as such, the sale or use of these products is subject to tax.

(6) *Vitamins, Minerals, Herbs, and Other Such Supplements.* In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(7) *Diagnostic Substances, Test Kits, and Equipment.* Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment, they are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines for the purposes of the exemption provided under Section 6369.

Tax also applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether or not they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

~~(f) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge therefor to patients.~~

~~(g) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:~~

~~————— “As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24 hour stay or longer,...”~~

~~Tax does not apply to sales by a health facility of medicines for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales to a health facility of medicines for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.~~

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~~(h) Insulin. “Insulin” and “insulin syringes” furnished by a registered pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369.~~

~~(i) Orthotic and Prosthetic Devices. Orthotic and prosthetic devices, and replacement parts for these devices, furnished pursuant to the written order of a licensed physician or podiatrist, shall be deemed to be dispensed on prescription within the meaning of paragraph (a)(1), whether or not the devices are furnished by a registered pharmacist.~~

~~(j) Mammary Prostheses and Ostomy Appliances and Supplies. Mammary prostheses, and any appliances and related supplies necessary as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste, shall be deemed to be dispensed on prescription within the meaning of Section 6369. Qualifying mammary prostheses and ostomy appliances and supplies include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover, belts, catheters used as a result of an artificial opening created in the human body, colostomy bags, deodorant used on the person of the user, karaya rings, antacid used externally as a skin ointment, skin gel, nonallergic paper tape and gauze, skin bond cement, tincture of benzoin applied topically as a protective, urinary drainage appliances, closed stoma bags, drainable stoma bags, loop ostomy supplies, and tubing.~~

~~The term “appliances” and “related supplies” includes kidney dialysis machines, and the tubing, pumps, blood sets, fistula sets, and shunts used in conjunction with such machines.~~

~~(k) Wheelchairs, Crutches, Canes, Quad Canes and Walkers. Tax does not apply to sales, including leases that are “sales,” of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, and walkers and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician.~~

~~(l) Modifications to Vehicles used by Physically Handicapped Persons. Tax does not apply to the sale of items and materials used to modify a vehicle for physically handicapped persons which are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. The exemption does not extend to tools and supplies used in modifying the vehicle and not incorporated into, attached to, or installed on the vehicle.~~

~~In the case of a sale of a modified vehicle to a physically handicapped person, tax does not apply to the gross receipts attributable to that portion of the vehicle which has been modified to enable the vehicle to be used to transport a physically handicapped person or persons.~~

~~—(1) The term, “physically handicapped” persons, as used in this section, includes disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.~~

~~—(2) The term, “vehicle,” as used in this section, includes all devices which qualify under Vehicle Code Section 670 as “vehicles” including but not limited to automobiles, vans, trucks, mobilehomes and trailercoaches.~~

~~—(3) “Vehicles” qualifying under this section mean and include:~~

~~—(A) Vehicles which are owned and operated by physically handicapped persons.~~

~~—(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.~~

~~(m) Medical Oxygen Delivery Systems. Tax does not apply to the sale of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. “Medical oxygen delivery systems” includes liquid oxygen containers, high pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the person. The term also includes repair and replacement parts for use in such a system.~~

~~(n) Balloon Catheters. Sales of intra-aortic balloon pump catheters and coronary angioplasty balloon catheters are not subject to tax. Sales of related supplies are subject to tax. The term “related supplies” includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, hemostatic valves, inflation devices, and syringes.~~

~~(o)~~ Medical Insurance Payments

(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) Medicare

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the U.S. Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the U.S. Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the U.S. Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as an exempt sale of a medicine), the sale is subject to tax.

~~(p)~~ Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These

contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(gg) Records.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to Section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Section 6369:

- Name of purchaser
- Name of doctor
- Date of sale
- Item sold
- The sale price

(2) “Double Deduction” Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

History: Effective January 1, 1962.

Amended May 16, 1962.

Amended September 18, 1963, effective as amended September 20, 1963.

Amended and renumbered December 10, 1969, effective January 11, 1970.

Amended May 4, 1971, effective July 1, 1971.

Amended September 14, 1972, effective September 15, 1972.

Amended January 18, 1973, effective January 26, 1973.

Amended October 20, 1977, effective October 28, 1977. Changed to conform to Revenue and Taxation Code Section 6369 and 6369.2. Added orthotic and prosthetic devices to definition of “medicines;” excluded “dentures” from the definition of “medicines;” added mammary prostheses and ostomy appliances to items to be dispensed on prescription; added wheelchairs, crutches, canes, quad

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canes and walkers as exempt items. Changed all references to the term “hospital” to “health facility” as defined in Section 1250 of the Health and Safety Code.

Amended March 1, 1978, effective April 29, 1978. In (b)(4) added list of specific orthotic devices; in (b)(5) added list of prosthetic devices; in (c)(1), (2) and (3) included specific items excluded from the term “medicines”; in (g) made grammatical change; in (i) added list of specific items to be included under this section; in (j) added leases to transactions to which tax does not apply and provided that tax applies to all replacement parts; in (m) deleted references to former Section 280 of Title 17, California Administrative Code, and added (1) specifying acceptable documentation for exempt sales and (3) suggesting use of Regulation 1667 “Exemption Certificates.”

Amended July 27, 1978, effective July 31, 1978. In (b)(5) deleted dental crowns, caps and inlays from definition of “medicines”; in (c)(1) added crowns, caps, inlays and other dental prosthetic materials and devices to exclusions from term “medicines”; in (c)(2) added orthodontic appliances to exclusions from term “medicines”; in (i) provided that orthotic and prosthetic devices shall be deemed to be dispensed on prescription; in (k) exempted replacement parts for wheelchairs, crutches, canes, quad canes and walkers from tax.

Amended September 27, 1978, effective November 18, 1978. In (b)(5) added intraocular lenses and ear implants; moved general exclusionary language from (c)(3) to (c); to (c)(2) added reference to footnote 3; and added reference to orthodontic appliances and devices to footnote 3.

Amended September 26, 1979, effective November 16, 1979. Adds (1); reletters former (1) and following subsection.

Amended July 27, 1983, effective November 17, 1983. Added subdivision (b)(7); changed reference in first sentence of (c) from (b)(6) to (b)(7). Added “and, on or after January 1, 1983, “insulin syringes” to subdivision (h) and added subdivision (m); relettered former subdivisions (m), (n), (o) to (n), (o), (p).

Amended August 24, 1988, effective October 7, 1989. In subdivision (b)(4) added provisions to include “custom made biomechanical foot orthoses” within the definition of the term medicines.

Amended October 26, 1993, effective February 17, 1994. Amended subdivision (k) to provide the exemption from tax for white canes used by the legally blind; removed obsolete dates in subdivisions (b)(4), (b)(7), (h), and (m).

Amended June 27, 1996, effective August 23, 1996. Amended subdivisions (b)(4) and (5) to correct spelling errors; added new subdivision (n), and renumbered former subdivisions (n), (o), and (p) as (o), (p), and (q), respectively.

Amended November 19, 1996, effective December 19, 1996. Added new (a)(7) to incorporate provisions of Assembly Bill 3836 (Chapter 857, Statutes of 1994).

Amended August 10, 1998, effective October 17, 1998. Amended subdivisions (a)(6), (d), (e) to reflect changes in sections of the Business and Professions Code; corrected spelling errors in subdivisions (b)(4)(A) and (b)(5); changed “which” to “that” in subdivision (g); removed obsolete date in subdivision (k); amended subdivisions (l)(1) and (l)(3)(B) to reflect changes in sections of the California Vehicle Code.

REGULATION 1591.1. SPECIFIC MEDICAL DEVICES, APPLIANCES, AND RELATED SUPPLIES(a) Definitions.

(1) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(2) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(b) Specific Applications.

(1) Hemodialysis Products. Tax does not apply to the sale or use of hemodialysis products supplied on order of a licensed physician and surgeon to a patient by a pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to the patient. _____

(2) Mammary Prostheses and Ostomy Appliances and Related Supplies. Tax does not apply to the sale or use of mammary prostheses and ostomy appliances and related supplies required as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste when sold or furnished under one of the conditions provided in Regulation 1591 subdivision (d)(1) through (d)(6). The mammary prostheses devices and ostomy appliances and related supplies do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as they are furnished pursuant to a written order of a person authorized to prescribe.

Ostomy appliances and related supplies must be used in postoperative situations or sold as an accommodation to patients following surgery in order to qualify as medicines. When used as an adjunct to surgical procedures, the sale or use of these items is subject to tax unless the appliances remain in the patient for postoperative purposes.

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Qualifying mammary prostheses and qualifying ostomy appliances and related supplies include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover; catheters used as a result of an artificial opening created in the human body; colostomy bags; deodorant used on the person of the user; karaya rings; antacid used externally as a skin ointment; skin gel; nonallergic paper tape and gauze; skin bond cement; tincture of benzoin applied topically as a protective; urinary drainage appliances; closed stoma bags; drainable stoma bags; loop ostomy supplies and tubing; and endotracheal and tracheotomy tubes used for the evacuation of metabolic waste when used post-operatively or for home care. Tracheostomy tubes used to facilitate the passage of air do not qualify as medicines for the purposes of Section 6369.

Kidney Dialysis Machines. The term “ostomy appliances” and “related supplies” includes kidney dialysis machines, replacement parts for the kidney dialysis machines, and the catheters, dialysis fluid additives, volumetric infusion pumps, tubing, blood sets, fistula sets, and shunts used in conjunction with such machines. In order to qualify as a “related supply,” an item must be a necessary and integral part of the machine itself, or a substance or preparation intended for external or internal application to the human body of the patient undergoing dialysis.

(3) Catheters. Generally, sales of catheters are subject to tax in the same manner as other sales of tangible personal property. However, sales of the following types of catheters are not subject to tax.

(A) Intra-aortic balloon pump catheters and coronary angioplasty balloon catheters.

However, sales of related supplies are subject to tax. The term “related supplies” includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, hemostatic valves, inflation devices, and syringes.

(B) Catheters which are permanently implanted in the human body and assist the functioning of a natural organ, artery, vein, or limb and remain or dissolve in the body.

(C) Catheters used for drainage purposes through which an artificial opening is created in the human body. Such catheters qualify as ostomy materials and related supplies.

(D) Catheters or similar types of devices used for drainage purposes through natural openings in the human body to assist or replace the functioning of a natural part of the human body. Such catheters are designed to be worn on or in the body of the user and qualify as prosthetic devices.

(4) Insulin and Insulin Syringes. “Insulin” and “insulin syringes” furnished by a pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369(e). As such, the sale or use of insulin and insulin syringes furnished by a pharmacist to a person for treatment of diabetes, as directed by a physician, is exempt from tax.

However, the exemption provided under Section 6369(e) does not apply to the sale or use of glucose monitoring systems. Blood glucose monitors, glucose test strips, lancets, and other related items are used by a patient to monitor and test his or her blood sugar level, they are not applied to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease. Since the system and related items do not qualify as medicines or come under the exemption provided by Section 6369(e), their sale

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or use is subject to tax regardless of whether or not they are furnished pursuant to the direction of a licensed physician.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.1, Revenue and Taxation Code.

REGULATION 1591.2. WHEELCHAIRS, CRUTCHES, CANES, AND WALKERS.(a) Definitions.

(1) Physician. For purposes of this regulation, “physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. Physician, as defined, includes doctors of medicines (MD), doctors of osteopathy (DO), and doctors of podiatric medicine (DPM).

(2) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(3) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”

(b) Tax Application. Tax does not apply to the sale or use, including leases that are continuing sales and purchases, of wheelchairs; crutches; canes; quad canes; white canes used by the legally blind; walkers; and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician. Electric three-wheel scooters that are similar in both design and function to a conventional electric wheelchair, qualify as a wheelchair for the purposes of Section 6369.2. When the scooters are sold or leased to an individual for the personal use of that individual as directed by a licensed physician their sale or use qualifies for an exemption from tax.

“Replacement parts” include, but are not limited to, batteries for electric wheelchairs; belts and cushions sold to replace or supplement the basic items originally sold with wheelchairs, lap boards and trays attached to wheelchairs and considered a part of the wheelchair; and rubber tips, wheels, and other such items prescribed for an individual to replace an original component of the device sold. “Replacement parts” do not include items such as mechanical devices that aid the patient in eating or writing unless the items are part of the device itself, or restraints or other such items sold to an individual, but which do not become a part of the wheelchair or other such prescribed device.

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(c) Sales to Health Facilities. Sales, or leases that are continuing sales and purchases, of wheelchairs, crutches, canes, and walkers to hospitals or other health facilities for use by patients while at the facilities are subject to tax. Such sales or leases are not considered sold to an individual for the individual's personal use as directed by a physician. However, when wheelchairs, crutches, canes, and walkers are ordered by a hospital or health facility on behalf of a specific patient, as directed by a physician, the items may be considered to be purchased by an individual for his or her own personal use as required under Section 6369.2 and, therefore, the sale will qualify for exemption from tax.

(d) Sales to Insured Persons. The exemption for qualifying retail sales of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, walkers, and replacement parts for these devices is not affected by the fact that charges to the individual to whom such items are sold, may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.2, Revenue and Taxation Code.

REGULATION 1591.3. VEHICLES FOR PHYSICALLY HANDICAPPED PERSONS.

(a) Definitions.

(1) Physically Handicapped Persons. For purposes of this regulation, “physically handicapped” persons include disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.

(2) Vehicle. For purposes of this regulation, “vehicle” includes all devices that qualify under Vehicle Code Section 670 as “vehicles” including, but not limited to, automobiles, vans, trucks, mobilehomes and trailercoaches. “Vehicles” qualifying under this regulation mean and include:

(A) Vehicles which are owned and operated by physically handicapped persons and,

(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.

(b) Application of Tax. Tax does not apply to the sale or use of items and materials used to modify a vehicle for physically handicapped persons when such items are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. However, sales or purchases of tools and supplies used in modifying the vehicle and which are not incorporated into, attached to, or installed on the vehicle are subject to tax.

Items and materials considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an interlock system; upper torso restraint; an airbag of a unique type to raise or lower the vehicle for loading or unloading; running boards on lower side of vehicle; a bolt cam used to restrain a wheelchair inside a van; seat belts; a tire carrier to hold a spare and which is installed within reach of a handicapped person; AC lights to illuminate the ramp or elevator area; hardware for privacy curtains; air compressor for use with medical equipment; a 12-volt receptacle to supply power to medical equipment; a 4-point tie down system to restrain a wheelchair; and an allocable portion(s) of the various interior packages, interior materials, and conversions necessary to modify the vehicle for transport of physically handicapped persons.

Items and materials that are generally not considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an upper torso durable pad (unless part of the restraint); portable ramps (telescopic); air conditioners (unless necessary for the transport of certain types of disabled persons); a fire extinguisher; a CB radio (unless shown to be necessary to the transport of certain types of disabled persons); leather seat covers; extra windows and their accessories; upgrades to the interior (upgrade to leather seats); and an engine cover. The sale or use of such items, whether installed on a vehicle to be used for transport of physically handicapped persons or not, are generally subject to tax.

(c) Sales of Modified Vehicles. Tax does not apply to the gross receipts attributable to the portion of a vehicle that has been modified to enable the vehicle to be used to transport a physically handicapped person or persons when the modified vehicle is sold to a physically handicapped person, as defined.

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(d) Repairs to Modified Vehicles. Tax does not apply to the sale or use of items and materials used to repair the modified portion (the portion that contains equipment previously used to modify the vehicle) of a vehicle used to transport a physically handicapped person or persons. Once installed, such "repair parts" qualify as items and materials used to modify a vehicle in order for the vehicle to be used to transport a physically handicapped person or persons.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.4, Revenue and Taxation Code.

REGULATION 1591.4. MEDICAL OXYGEN DELIVERY SYSTEMS.(a) Definitions.

(1) Physician. "Physicians" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(3) Health Facility. "Health Facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(4) Medical Oxygen Delivery System. A system used to administer oxygen directly into the lungs of the patient for the relief of conditions in which the human body experiences an abnormal deficiency or inadequate supply of oxygen. Devices that only assist the patient in breathing, but do not deliver air or oxygen directly into the lungs of the patient, do not qualify as medical oxygen delivery systems.

(b) Tax Application.

(1) Medical Oxygen Delivery Systems. Tax does not apply to the sale or use of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. Medical oxygen delivery systems include, but are not limited to, liquid oxygen containers, high-pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the patient. The term also includes repair and replacement parts for use in such a system.

(2) Ventilators and Other Respiratory Equipment. For the purposes of this regulation, ventilators that produce a form of controlled respiration in which compressed air is delivered under positive pressure into the patient's airways qualify for the exemption provided under Section 6369.5 for medical

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oxygen delivery systems. Pressure ventilators and volume ventilators provide assisted respiration and intensive positive pressure in which compressed air, a component of which is oxygen, is administered into the breathing systems of patients to help them breathe. The sale or use of ventilators, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician

Respiratory equipment that induces air into the lungs of a patient, through the application of pressure to the chest area, also qualifies for the exemption provided for medical oxygen delivery systems, regardless of whether the pressure applied is negative pressure or positive pressure. The sale or use of respiratory equipment, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician. Included within the scope of the exemption are exsufflation belts, iron lungs, chest shells, pulmo wraps, and the pumps and regulators necessary for the operation of the listed equipment.

(c) Sales to Health Facilities and Health Care Providers. Sales of medical oxygen delivery systems are exempt when sold to an individual for his or her own use under the direction of a licensed physician. Sales of medical oxygen delivery systems to hospitals, immediate care facilities, physicians, or other health care providers for use on their premises are subject to tax in the same manner as other sales of tangible personal property.

A rental or lease of a medical oxygen delivery system to a health facility qualifies for an exemption from tax when the facility intends to lease or rent the system to an individual for the personal use of that individual as directed by a licensed physician and the system is then leased or rented as intended. However, the transaction between the health facility and the individual must constitute an actual lease or rental. When the patient's use of the medical delivery system is limited to the health facility's premises, the direction and control of the equipment does not transfer to the patient. Therefore, an actual lease or rental of the system to the patient does not occur even when a separate billing is made to the patient for the use of the system. As such, the lease or rental of the system to the health facility does not qualify for the exemption provided under Section 6369.5.

(d) Sales of Medical Oxygen. Medical oxygen and other gases sold to a licensed physician and surgeon, podiatrist, dentist, or health facility for treatment of human beings are considered medicines. Therefore, their sale or use is not subject to tax when (1) furnished by a licensed physician and surgeon, podiatrist, or dentist to his or her own patient or (2) furnished by the health facility pursuant to the order of a licensed physician and surgeon, dentist, or podiatrist.

Medical oxygen sold by distributors of compressed gases to an individual for use as part of the individual's treatment, pursuant to a physician's prescription, is regarded as a medicine furnished by a licensed physician to his or her own patient for treatment of the patient as provided by Regulation 1591(b)(2). Sales of medical oxygen to individuals under the "Casey Bill" (i.e., the retailer bills the service acting as a fiscal agent for the State of California) are regarded as sales of medicines to this State for use in the treatment of human beings as provided by Regulation 1591(b)(5). Therefore, sales of medical oxygen by such distributors, under these conditions, are not subject to tax whether or not the distributor is a medical supply house.

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(e) Sales to Insured Persons. The exemption for qualifying retail sales of oxygen delivery systems and replacement parts is not affected by the fact that charges to the individual for whom such items are sold, leased, or rented may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.5, Revenue and Taxation Code.

Revised July 5, 1999

Revised regulation draft with explanatory language and cited, pertinent annotations. The following format was used to illustrate the type and extent of changes that were made.

Board of Equalization
SALES AND USE TAX REGULATIONS

References: Sections 6006, 6369, 6369.1, 6369.2, 6369.4, and 6369.5 Revenue and Taxation Code.

Regulation 1591. MEDICINES AND MEDICAL SUPPLIES, DEVICES AND APPLIANCES.

(a) GENERAL. Tax applies to retail sales of drugs, medicines, and other tangible personal property by pharmacists and others except as follows:

Tax does not apply to sales of medicines for the diagnosis, cure, mitigation, treatment or prevention of disease of a human being, which are commonly recognized as a substance, preparation for that use, and which are:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines and are dispensed on prescription filled by a ~~registered~~ pharmacist in accordance with law, or as otherwise set forth in these regulations, or
THE TERM "REGISTERED" IS DELETED AS AN OBSOLETE TERM TO DESCRIBE A PHARMACIST. LANGUAGE ADDED TO ACCOMMODATE THE DISPENSING ON PRESCRIPTION OF PROSTHOTIC OR ORTHOTIC DEVICES BY A MEDICAL SUPPLY DEALER. AS WELL AS THE FURNISHING OF WIGS

(2) furnished by a licensed physician, dentist, or podiatrist to his or her own patient for treatment of the patient. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge. or
THE LANGUAGE INSERTED HERE AND UNDERLINED IS THE UNCHANGED LANGUAGE OF EXISTING REGULATION 1591 (f) THAT WAS INADVERTENTLY OMITTED AND IS PLACED HERE AS THE APPROPRIATE PLACE IN THE ASSOCIATIONS PROPOSED REFORMATTING.

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist, or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by the state or any political subdivision or municipal corporation thereof.

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (a)(6)(7) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

EXCEPT FOR THE CHANGE IN REFERENCE TO (a)(7) AND ITS CHANGE TO (A)(6), THE LANGUAGE IS UNCHANGED. THE REFERENCE WAS CHANGED FOR CORRECT SEQUENCING IN THE REFORMATTING. THIS SECTION WAS INADVERTENTLY OMITTED IN THE ORIGINAL DRAFT.

(b). Any medicine which is dispensed, furnished, or administered for the care of a patient in compliance with any of the conditions set forth in paragraph (a)(1) through (a)(5) above shall be deemed to be a critical component in the delivery of medically necessary care to that patient.

LANGUAGE ADDED TO REFLECT THE IMPORTANCE OF THE ITEMS SUPPLIED AS MEDICINES TO THE MEDICAL CARE OF THE PATIENT.

(c) Any medicine which is tax exempt, when sold or furnished under any one of the conditions set forth in subparagraph (a)(1) through (a)(5) above, is equally tax exempt if sold or furnished under any of the other conditions set forth above.

LANGUAGE ADDED TO CLARIFY THE APPLICATION OF THESE REGULATIONS TO THE USER.

(d) Sales of medicines not meeting the definitions in subparagraph (d) sold to or by health practitioners or facilities are not exempt from tax, provided, however, if subsequent sales to patients meet the applicable requirements set forth in subparagraph (a) above, the sales would be exempt.

LANGUAGE ADDED TO CLARIFY THE APPLICATION OF THESE REGULATIONS TO THE USER

(e)(a) DEFINITIONS. of "Medicines"

(1) The term "Medicines" means and includes:

a. Any substance or preparation, including dangerous drugs, intended for use by external or internal application to the human body, and its parts, including blood and urine, in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

LANGUAGE ADDED PROVIDE FOR DANGEROUS DRUGS AND TO CLARIFY THAT THE DEFINITION APPLIES TO BODY PARTS AS WELL.

b. Any medical supply, prosthetic or orthotic device, medical device or appliance, meeting the above definition of a medicine, and which meets the requirements of the applicable regulation sections which follow.

LANGUAGE ADDED TO FACILITATE THE REFORMATTING OF THE REGULATIONS INTO INDIVIDUAL COMPONENTS WHICH AFFECT SPECIFIC CLASSES OR CATEGORIES OF MEDICINES. THE DEFINITION BECOMES PART OF THE SUBSECTION CONTAINING ALL DEFINITIONS.

(2) The term "Pharmacist" is defined under Section 4036 of the Business and Professions Code as follows:

"Pharmacist" means a person to whom a license has been issued by the board, under Section 4200 except as specifically provided otherwise in this chapter."

THE LANGUAGE OF THIS REGULATION IS ADDED TO THE EXPANDED SUBSECTION ON DEFINITIONS AND REFLECTS THE CURRENT LANGUAGE OF THE BUSINESS AND PROFESSIONS CODE. THIS LANGUAGE HAS BEEN MOVED TO THE DEFINITION SUBSECTION FOR CONSISTENCY IN REFORMATTING.

(3) The term "Prescription" is defined under Section 4040 of the Business and Professions Code as follows:

"Prescription" means an oral, written, or electronic transmission order that is both of the following:

A. given individually for the person or persons for whom ordered that includes all of the following:

I. The name or names and address of the patient or patients.

II. The name and quantity of the drug or device prescribed and the directions for use.

III. The date of issue.

IV. Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

V. A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

VI. If in writing, signed by the prescriber issuing the order.

B. Issued by a physician, dentist,or podiatrist.....licensed in this state."

THE LANGUAGE OF THIS REGULATION IS ADDED TO THE EXPANDED SUBSECTION ON DEFINITIONS AND REFLECTS THE CURRENT LANGUAGE OF THE BUSINESS AND PROFESSIONS CODE. THIS LANGUAGE HAS BEEN MOVED TO THE DEFINITION SUBSECTION FOR CONSISTENCY IN REFORMATTING.

(4) Physician; Other Practitioners.

Physicians and other practitioners are defined by Section 4039 of the Business and Professions Code as follows:

“Physicians,” “dentists,”or “podiatrists”are persons authorized by a currently and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California.

LANGUAGE ADDED TO PROVIDE CURRENT BUSINESS AND PROFESSIONS CODE DEFINITIONS OF PHYSICIAN AND OTHER PRACTITIONERS WHICH WAS NOT INCLUDED PREVIOUSLY. LANGUAGE IS PLACED HERE IN THE DEFINITION SUBSECTION.

(5) Health Facility.

“Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter, “health facility” means any facility, place or building which is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24 hour stay or longer...”

LANGUAGE IS THAT OF THE EXISTING DEFINITION IN CURRENT SECTION 1591 BUT PLACED HERE AS PART OF THE NEW SUBSECTION ON DEFINITIONS.

(6) Medical Device Retailer

“Medical Device Retailer” is defined by Section 4034 of the Business and Professions Code as follows:

A. “Medical Device Retailer” is an area, place, or premises, other than a pharmacy, in which dangerous devices are sold, fitted, or dispensed pursuant to a prescription.

“Medical device retailer” includes, but is not limited to, any area, place or premises described in the license issued by the Board of Pharmacy wherein dangerous devices are stored, possessed, prepared, manufactured, or repackaged, and from which the dangerous devices are furnished, sold or dispensed at retail.

B. “Medical Device Retailer” shall not include those exemptions set forth in paragraphs (b) and (c) of Section 4034 of the Business and Professions Code.

LANGUAGE ADDED TO REFLECT STATUTORY REQUIREMENTS FOR PLACES WHICH MAY SELL, FIT, OR FURNISH MEDICAL DEVICES AND IS PLACED HERE IN THE NEW SUBSECTION ON DEFINITIONS.

(7) Dangerous Device

“Dangerous Device” is defined by Sections 4022 (b) and (c) of the Business and Professions Code as follows:

A. “Dangerous Device” is any device that bears the statement: “Caution: federal law restricts this device to sale by or on the order of a “(physician, dentist, or podiatrist)” or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

B. Any other device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 of the Business and Professions Code.

LANGUAGE ADDED TO PROVIDE A DEFINITION OF DANGEROUS DEVICES FOR USE IN LATER APPLICABLE SECTIONS OF THESE REGULATIONS. IT IS PLACED HERE IN THE SUBSECTION ON DEFINITIONS.

(8) Medical Supplies

“Medical Supplies” are health-related items which do not require a prescription for their general purchase, but, when, in the professional opinion of a physician, podiatrist, or dentist, their use is a critical component in the delivery of medical care to his or her patient, are prescribed for that patient’s use.

NEW LANGUAGE ADDED TO SUPPLY A TERM USED IN THE TITLE OF THIS REGULATION BUT NOT OTHERWISE DEFINED. IT IS IN COMMON USE IN THE HEALTH CARE FIELD AND THIS DEFINITION WILL PROVIDE A REFERENCE POINT FOR ITS USE IN THE REGULATION. IT IS PLACED HERE IN THE SUBSECTION ON DEFINITIONS FOR CONSISTENCY IN REFORMATTING.

(9) Dangerous Drugs

A. “Dangerous drug” means any drug unsafe for self-use, and includes the following:

1. Any drug that bears the legend: “Caution: federal law prohibits dispensing with prescription” or words of similar import.

2. Any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 of the Business and Professions Code. APPLICABLE LANGUAGE FROM THE CURRENT BUSINESS AND PROFESSIONS CODE IS ADDED TO DEFINE TERMS USED LATER IN THESE REGULATIONS AND IS PLACED HERE IN THE SUBSECTION ON DEFINITIONS.

~~(2) bone screws, bone pins, pacemakers, and other articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body. The term also includes sutures, whether or not permanently implanted. A nonreturnable, nonreusable needle fused or prethreaded to a suture is regarded as a part of the suture.~~

~~(3) artificial limbs, or their replacement parts, for human beings including stump socks and stockings worn with an artificial leg.~~

~~(4) orthotic devices, or their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure; provided, that orthopedic shoes and supportive devices for the foot are not exempt unless they are an integral part of a leg brace or artificial leg or, are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device which is made on a positive model of the individual patient’s foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology. The device described above excludes 1) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification; 2) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of~~

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~~manufacture and materials used and regardless of its individual character. “Orthotic devices” includes, but is not limited to, abdominal binders, ace bandages, ankle braces, anti-embolism stockings, casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers, rib belts and immobilizers, rupture holders, sacral belts, sacra-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, support hose (and garter belts used to hold them in place), trusses, and wrist and arm braces.~~

~~(5) prosthetic devices, or their replacement parts, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body, other than auditory, opthalmic and ocular devices or appliances, and other than dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth and other dental prosthetic materials and devices.~~

~~(6) artificial eyes, or their replacement parts, intraocular lenses for human beings, and ear implants.~~

~~(7) programmable drug infusion devices to be worn on or implanted in the human body which automatically cause the infusion of measured quantities of a medicine into the body of the wearer of the device.~~

~~(c) EXCLUSIONS FROM TERM “MEDICINES”. Except as otherwise provided in (b)(2) through (b)(7) above, the following items are excluded from the term “medicines”:~~

~~(1) Orthodontic, prosthetic, auditory, opthalmic or ocular devices or appliances.~~

~~(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.~~

~~(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).~~

~~(d) WHO IS A “REGISTERED PHARMACIST”. A “registered pharmacist” is defined under Section 4037 of the Business and Professions Code as follows:~~

~~“Registered pharmacist” means a person to whom a certificate has been issued by the board, under provisions of Section 4085.”~~

~~(e) WHAT CONSTITUTES A “PRESCRIPTION”. Section 4036 of the Business and Professions Code defines “prescription” as follows:~~

~~“Prescription” means an oral order given individually for the person or persons for whom prescribed, directly from the prescriber to the furnisher, or indirectly by means of a written order, signed by the prescriber, and shall bear the name or names and address of the patient or patients, the name and quantity of the drug or device prescribed, directions for use, and the date of issue, and either rubber stamped, typed or printed by hand or typeset the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed....”~~

~~No person other than a licensed physician, dentist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being.~~

~~(f) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge therefor to patients.~~

~~(g) HEALTH FACILITY. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:~~

~~“As used in this chapter “health facility” means any facility, place or building which is organized, maintained and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24 hour stay or longer.~~

~~Tax does not apply to sales by a health facility of medicines for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales to a health facility of medicines for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.~~

~~(h) INSULIN. “Insulin” and “insulin syringes” furnished by a registered pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369.~~

~~(i) ORTHOTIC AND PROSTHETIC DEVICES. Orthotic and prosthetic devices, and replacement parts for these devices, furnished pursuant to the written order of a licensed physician or dentist, shall be deemed to be dispensed on prescription with the meaning of paragraph (a)(1), whether or not the devices are furnished by a registered pharmacist.~~

~~(j) MAMMARY PROSTHESES AND OSTOMY APPLIANCES AND SUPPLIES. Mammary prostheses, and any appliances and related supplies necessary as a result of any surgical procedure by which an artificial opening is created in the human body for the~~

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~~elimination of natural waste, shall be deemed to be dispensed on prescription within the meaning of Section 6369. Qualifying mammary prostheses and ostomy appliances and supplies include, but are not limited to bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover, belts, catheters used as a result of an artificial opening created in the human body, colostomy bags, deodorant used on the person of the user, karaya rings, antacid used externally as a skin ointment, skin gel, nonallergic paper tape and gauze, skin bond cement, tincture of benzoin applied topically as a protective, urinary drainage appliances, closed stoma as, drainable stoma bags, loop ostomy supplies, and tubing.~~

~~The term “appliances” and “related supplies: includes kidney dialysis machines, and the tubing, pumps, blood sets, fistula sets, and shunts used in conjunction with such machines.~~

Regulation 1591.1 Drugs and Medicines

The following items are exempt unless otherwise indicated:

(a) Drugs and medicines, including both dangerous drugs and those which do not qualify as such, but which meet any of the requirements of Section 1591 (a)1 through (a)6.

1.. Exempt medicines that are not dangerous drugs may include, but are not limited to, the following: antiseptics, baby powder, emollients and antipruritic lotions, liquid castile soap, lubricating jelly, medicated pads or dressings, medicated skin creams, moisturizing lotions, rubbing alcohol, skin cleanser/antiseptics, skin bleaching/sun protein products, sterile water, sun screens, surgical soaps, and vitamins.

LANGUAGE ADDED TO CLARIFY THE SCOPE OF EXEMPT AND NON-EXEMPT ITEMS BY SUBDIVIDING THEM INTO SEPARATE SECTIONS.

ANNOTATIONS 425.0132, 425.0166, 425.0180, 425.0188, 425.0210, 425.0211, 425.0227, 425.0248, 425.0250, 425.0489.890, 425.0514, 425.0522, 425.0531, 425.0699, 425.0730, 425.0780, 425.0823.100, 425.0823.5, 425.0880, 425.0900, 425.0167.500, 425.1140, 425.1170.

(b) Insulin and Insulin syringes furnished by a pharmacist to a person for treatment of diabetes as directed by a physician. These items shall be deemed to be medicines dispensed on prescription within the meaning of Section 6369.

1. Blood monitoring equipment, glucose test strips and related supplies used by diabetic patients to determine his/her blood sugar level are exempt.

NEW LANGUAGE HAS BEEN ADDED TO THE EXISTING REGULATORY LANGUAGE OF EXISTING SECTION 1591(h) ON INSULIN AND INSULIN SYRINGES IN ORDER TO REFLECT ADDITION OF “BODY PARTS” TERMINOLOGY IN THE DEFINITION OF MEDICINES.

2. Hypodermic needles and syringes used to administer drugs and medicine other than insulin, are not exempt.

LANGUAGE ADDED TO EMPHASIZE AND ILLUSTRATE THE EXCLUSION OF THESE PRODUCTS

ANNOTATIONS 425.0420, 425.0462, 425.0463

(c) Hemodialysis products supplied on order of a licensed physician to a patient by a registered pharmacist or by a manufacturer, wholesaler, or other supplier authorized by

Section 4050.7 or 4227 4054 of the Business and Professions Code to distribute such products directly to a hemodialysis patient.

EXISTING LANGUAGE OF SECTION 1591 PLACED HERE FOR CONSISTENCY IN SUBJECT MATTER AND MODIFIED TO REFLECT CURRENT APPLICABLE SECTIONS OF THE BUSINESS AND PROFESSIONS CODE.

(d) The terms “Drugs” or “Medicines” do not include any of the following:

1. Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code). Such beverages shall not be exempt.

2. Placebos used in place of an exempt drug or medicine.

EXISTING LANGUAGE OF SECTION 1591 PLACED HERE FOR CONSISTENCY IN SUBJECT MATTER. LANGUAGE IS ALSO ADDED TO EMPHASIZE THE LACK OF EXEMPTION AND TO REFLECT CURRENT ANNOTATIONS ANNOTATION 425.0028

Regulation 1591.2 Orthotic Devices

(a) Orthotic devices, or their replacement parts, designed to be worn on the person of the user as a brace, support, or correction for the body structure are exempt; provided, that orthopedic shoes and supportive devices for the foot are not exempt unless they are an integral part of a leg brace or artificial leg or, are custom-made biomechanical foot orthoses.

1. “Custom-made biomechanical foot orthoses” means a device which is made on a positive model of the individual patient’s foot. The model may be individually constructed from a suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology. The device described above excludes 1) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification; 2) any foot orthosis fabricated directly on the patient’s foot regardless of the method and materials used and regardless of its individual character; and 3) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of manufacture and materials used and regardless of its individual character.

THIS SECTION INCORPORATES EXISTING LANGUAGE OF SECTION 1591(b)

(4) ON THIS SUBJECT AND PLACES IT HERE FOR EASE OF USE AND CONSISTENCY OF REFORMATTING.

(b) The term “orthotic devices” includes, but is not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative and other knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, slump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the patient and be acting as a brace, support or correction for body structure.

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Those parts of devices which require partial support on other than the patient's body are taxable

THIS LANGUAGE INCORPORATES THE REMAINING LANGUAGE OF THE EXISTING 1591(4). ADDITIONAL LANGUAGE OR ITEMS WERE ADDED TO REFLECT CURRENT APPLICABLE ANNOTATIONS: ABDOMINAL SUPPORTS, ATHLETIC SUPPORTERS, "AND OTHER" KNEE BRACES, LEGGING ORTHOSES, STERNUM SUPPORTS, AND THUMB AND FINGER SPLINTS. QUALIFYING CONDITIONS FOR SUCH PRODUCTS TO BE EXEMPT ARE ADDED.

ANNOTATIONS 425.0162, 425.0168.300, 425.0178.800, 425.0269.800, 425.0522, 425.0615.350, 425.0856

(c) Orthotic and replacement parts for these devices, furnished pursuant to the written order of a licensed physician or podiatrist, shall be deemed to be dispensed on prescription with the meaning of Section 1591.1, paragraph (a)(1), whether or not the devices are furnished by a pharmacist.

1. Orthotic devices which qualify as dangerous devices may be dispensed on prescription only by a pharmacist or by a medical device retailer.

EXISTING LANGUAGE OF SECTION 1591(i) IS ADDED HERE FOR THE SAKE OF CLARITY AND CONSISTENCY. NEW LANGUAGE IS ADDED TO REFLECT THE DIVISION OF THE REGULATION INTO COMPONENT SECTIONS AND TO REFLECT CURRENT REQUIREMENTS OF THE BUSINESS AND PROFESSIONS CODE. THE WORD "REGISTERED" IS DELETED FROM THE TITLE OF A PHARMACIST AS IT IS AN OBSOLETE TERM.

Regulation 1591.3 Prosthetic Devices

(a) Prosthetic devices, or their replacement parts, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body, other than auditory, ophthalmic and ocular devices or appliances and other than dentures, removable or fixed bridges, crowns, caps, inlays, artificial and other dental prosthetic materials and devices, are exempt.

1. Prosthetic devices which qualify as dangerous devices may be dispensed on prescription only by a pharmacist or by a medical device retailer.

THIS SECTION ADOPTS EXISTING LANGUAGE OF SECTION 1591(b)(5) AND IS ADDED HERE TO REFLECT THE DIVISION OF THE REGULATION INTO COMPONENT SECTIONS. NEW LANGUAGE IS ADDED TO REFLECT CURRENT REQUIREMENTS OF THE BUSINESS AND PROFESSIONS CODE

(b) Prosthetic devices, and replacement parts for these devices, furnished pursuant to the prescription of a licensed physician or podiatrist, shall be deemed to be dispensed on prescription with the meaning of paragraph (a)(1) of Section 1591, whether or not the devices are furnished by a pharmacist.

EXISTING LANGUAGE OF CURRENT SECTION 1591(I) AS IT PERTAINS TO PROSTHETIC DEVICES IS ADDED HERE TO REFLECT THE DIVISION OF THE REGULATION INTO COMPONENT SECTIONS. NEW LANGUAGE IS ADDED TO

ATTACHMENT 1

BETTER DEFINE THE ACTUAL SECTION OF PARAGRAPH (a)(1). THE TERM “REGISTERED” IS DELETED FROM THE TITLE OF A PHARMACIST AS OBSOLETE.

(c) Prosthetic devices not subject to tax include, but are not limited to, the following:

(1) Neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces.

NEW LANGUAGE ADDED TO CLARIFY THE TYPES OF PROSTHETIC DEVICES NOT SUBJECT TO TAX AND TO REFLECT CURRENT ANNOTATIONS
ANNOTATIONS 425.0397, 425.0413, 425.0473, 425.0546, 425.0885, 425.0906, 425.0907, 425.0980

(2) Artificial eyes, or their replacement parts, intraocular lenses for human beings, and ear implants.

THIS LANGUAGE IS THE EXACT LANGUAGE OF EXISTING SECTION 1591(b)(6) AND IS PLACED HERE FOR CONSISTENCY OF REFORMATTING.

(3) Artificial limbs, or their replacement parts, for human beings, including stump socks and stockings worn with an artificial leg.

THIS LANGUAGE IS THE EXACT LANGUAGE OF EXISTING SECTION 1591(b)(3) AND IS PLACED HERE FOR CONSISTENCY OF REFORMATTING.

(4) Mammary prostheses. These shall be deemed to be dispensed on prescription within the meaning of Section 6369. Qualifying mammary prostheses include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, and lymphoedema arm sleeves.

THIS LANGUAGE IS THE EXACT LANGUAGE OF EXISTING SECTION 1591(J) AS IT RELATES TO MAMMARY PROSTHESES AND IS PLACED HERE FOR CLARITY AND CONSISTENCY OF REFORMATTING.

(5) Catheters or other types of drainage devices used for drainage through natural or artificial openings, fecal collection bags, leg drainage bags, biliary drainage bags and urinary incontinence pouches, if worn on the person of the user, are exempt

LANGUAGE MODIFIED FOR CLARITY AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0229.700, 425.0230, 425.0234, 425.0391

(d) Prosthetic devices which are subject to tax include, but are not limited to, air compression pumps and pneumatic garments, noninvasive temporary pace makers and vacuum/constriction devices to treat male impotency. Supplies relating to the use of coronary balloon catheters, such as coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, hemostatic valves, inflation devices and syringes, are not exempt.

LANGUAGE ADDED FOR CLARITY AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0170, 425.0384, 425.0907.500

Regulation 1591.4 Permanently Implanted Articles

(a) Definition

“Permanently implanted articles” means articles implanted in the human body to assist the functioning, as distinguished from replacing all or any part of any natural organ, artery, vein or limb and which remain or dissolve in the body and whose removal is not otherwise anticipated.

THE DEFINITION LANGUAGE IS THE EXACT LANGUAGE CONTAINED IN SECTION 1591 (b)(2). LANGUAGE ADDED TO ACCOMODATE UNANTICIPATED REMOVAL, TO REFLECT DIVISION OF THE REGULATION INTO COMPONENT PARTS, AND TO REFLECT CURRENT ANNOTATIONS
ANNOTATION 425.0163

(b) Permanently implanted articles include, but are not be limited to, artificial sphincters, bone screws, bone pins, permanently implanted catheters, implanted hydrocephalus devices including their pressure regulating components and reservoirs and catheters, implanted defibrillators and leads, pacemakers, surgical replacement lenses, sutures(whether or not permanently implanted) tendon implants, testicular gel implants and other similar articles, other than dentures, and are exempt. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

THIS LANGUAGE IS THE BALANCE OF EXISTING SECTION 1591(b)(2) LANGUAGE. LANGUAGE HAS BEEN ADDED TO REFLECT CURRENT ANNOTATIONS, i.e, ARTIFICIAL SPHINCTERS, PERMANENTLY IMPLANTED CATHETERS, IMPLANTED HYDROCEPHALUS DEVICES INCLUDING THEIR PRESSURE REGULATING COMPONENTS AND RESERVOIRS AND CATHETERS, IMPLANTED DEFIBRILLATORS AND LEADS, TENDON IMPLANTS AND TESTICULAR GEL IMPLANTS.

ANNOTATIONS 425.0010.001, 425.0230, 425.0234, 425.0418, 425.0430, 425.0830, 425.0881.300, 425.0870, 425.1165

(c) Implantable articles which are not tax exempt include, but are not limited to, Chemoport implantable fluid systems, Port-a-Caths, temporary myocardial pacing leads, and tissue and breast expanders.

LANGUAGE ADDED TO SERVE AS EXAMPLES OF NON-EXEMPT ARTICLES AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0168.040, 425.0247, 425.0724, 425.0881

Regulation 1591.5 Medical Devices, Supplies and Appliances

(a) Medical devices, supplies and appliances which meet the requirements of Section 1591 (a) and are not otherwise excluded are exempt.

LANGUAGE ADDED TO REFLECT DIVISION OF THE REGULATION INTO COMPONENT SECTIONS AND TO ADD CLARITY

(b) Programmable drug infusion devices to be worn on or implanted in the human body which automatically cause the infusion of measured quantities of a medicine into the body of the wearer of the device are exempt.

THIS LANGUAGE IS ALMOST THE EXACT LANGUAGE OF SECTION 1591 (b)(7)
THIS LANGUAGE IS PLACED HERE FOR CONSISTENCY IN THE REFORMAT-
TING PROCESS.

1. A programmable drug infusion device must be capable of being programmed to deliver the solution on an intermittent or continuous basis, at variable dose rates and at high or low fluid-volume.

NEW LANGUAGE IS ADDED TO DEFINE A PROGRAMMABLE DRUG INFUSION DEVICE AND TO REFLECT CURRENT ANNOTATIONS.

ANNOTATION 425.0742

2. Pumps that gravity feed or which are not worn on or implanted in the body of the patient are not exempt.

NEW LANGUAGE IS ADDED TO PROVIDE EXAMPLES OF NON-EXEMPT DEVICES AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATION 425.0054

(c) Any appliances and related supplies necessary as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste shall be deemed to be dispensed on prescription within the meaning of Section 6369 and are exempt.

1. Qualifying ostomy appliances and supplies include, but are not limited to adhesive spray and remover, belts, catheters used as a result of an artificial opening created in the human body, colostomy bags, deodorant used on the person of the user, karaya rings, antacid used externally as a skin ointment, skin gel, nonallergic paper tape and gauze, skin bond cement, tincture of benzoin applied topically as a protective, urinary drainage appliances, closed stoma bags, drainable stoma bags, loop ostomy supplies, tubing, and endotracheal and tracheostomy tubes used for the evacuation of metabolic waste when used post-operatively or for home care.

THIS PARAGRAPH IS THE EXACT LANGUAGE OF THE RELEVANT PORTION OF EXISTING SECTION 1591 (j) PLUS ADDITIONAL NEW LANGUAGE ADDED FOR CLARITY AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0883.810, 425.0883.875 AND 425.0883.900

(e) The terms “appliances” and “related supplies” which are exempt include kidney dialysis machines and replacement parts, and the catheters, dialysis fluid additives, volumetric infusion pumps, tubing, pumps, blood sets, fistula sets, and shunts used in conjunction with such machines and blood adsorptive substances and equipment for their use.

THIS LANGUAGE REFLECTS THE LAST TWO LINES OF SECTION 1591(j). THE LANGUAGE HAS BEEN MODIFIED FOR CLARITY AND ADDITIONAL ITEMS ADDED WHICH REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0388, 425.0409, 425.0486, 425.0487, 425.0506, 425.0743, 425.1103

1. Products which are not exempt include, but are not limited to, the following: dialysis equipment cleaning supplies, dialyzer reprocessing systems, items worn by technicians during the dialysis process, and substances used to test dialysis concentrates.

NEW LANGUAGE IS ADDED TO PROVIDE EXAMPLES OF NON-EXEMPT PRODUCTS WHICH REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0021, 425.0026, 425.0143.600, 425.0485, 425.1103

~~(f)(k)~~ Wheelchairs, Crutches, Canes, Quad Canes and Walkers. Tax does not apply to sales, including leases that are sales, of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, ~~(effective January 1, 1993)~~ and walkers and replacement parts for these devices when sold to the individual for the personal use of that individual as directed by a licensed physician or podiatrist.

AN OBSOLETE DATE IS REMOVED AND LANGUAGE IS ADDED FOR A PRESCRIBER LEGALLY AUTHORIZED TO PRESCRIBE SUCH ITEMS WITHIN THE SCOPE OF HIS OR HER PRACTICE

~~(g) (m)~~ Medical Oxygen Delivery Systems. Tax does not apply to the sale of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. "Medical oxygen delivery systems" include liquid oxygen containers, high pressure cylinders, regulators, oxygen concentrators, tubes, masks, and related items necessary for the delivery of oxygen to the person. The term also includes repair and replacement parts for use in such a system. THIS SUBSECTION IS PLACED HERE FOR CONSISTENCY IN REFORMATTING.

(h) Unless otherwise provided, the following medical devices, supplies and appliances are not exempt:

1. Orthodontic, prosthetic, auditory, ophthalmic or ocular devices or appliances.
2. Articles that are solely in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof.
3. Arch supports, cervical pillows, exercise weights(boots or belts), hospital beds, orthopedic shoes and supportive devices(unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes(custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units(other than those fully worn on the patient), thermophore pads, nor foot orthoses.

THE LANGUAGE OF THIS SECTION INCLUDES THE EXCLUSIONS FROM THE TERM "MEDICINES" CONTAINED IN EXISTING SECTION 1591(c)(1), (2) AND (3). LANGUAGE IS ADDED TO PROVIDE CLARITY AND THIS SECTION IS PLACED HERE FOR CONSISTENCY IN REFORMATTING SINCE THEY ARE ALL MEDICAL DEVICES, MEDICAL SUPPLIES OR MEDICAL APPLIANCES SPECIFICALLY EXCLUDED.

Regulation 1591.6 ~~(4)~~ Modifications to Vehicles Used by Physically Disabled Persons.

(a) Tax does not apply to the sale of items and materials used to modify a vehicle for physically handicapped persons which are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. The exemption does not extend to tools and supplies used in modifying the vehicle and not incorporated into, attached to, or installed on the vehicle.

THIS EXISTING LANGUAGE IS INCORPORATED HERE AS A NEW REGULATION SECTION FOR CONSISTENCY IN REFORMATTING.

(b) In the case of a sale of a modified vehicle to a physically handicapped person, tax does not apply to the gross receipts attributable to that portion of the vehicle which has been modified to enable the vehicle to be used to transport a physically handicapped person or persons.

THIS SUBSECTION IS PLACED HERE FOR CONSISTENCY IN REFORMATTING.

(c) Items which are exempt from tax, when used to modify a vehicle for a physically handicapped person include, but are not limited to, the following: air compressor for use with medical equipment, floor lights, interior wheelchair restraints, modified doors, running boards, seat belts, a 12 volt power receptacle, supplemental steps, tire carriers to hold spare tire in a place other than designed by the manufacturer, transmission interlocks to prevent going into drive or reverse while the doors are open and /or a ramp is out for loading/unloading, upper torso restraints, wheelchair lifts, including repairs of all of the preceding items. Tax does not apply to installation or repairs of items and materials used to modify the vehicle.

THIS LANGUAGE IS ADDED TO PROVIDE EXAMPLES OF EXEMPT ITEMS AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0163.500, 425.0168.175, 425.0883.700, 425.0970, 425.1117

(c) Items which are not exempt from tax, when used to modify a vehicle for a physically handicapped person include, but are not limited to the following: air conditioners, CB radios, engine cover, fire extinguishers, leather seat covers, portable ramps, windows and their accessories, and tools and supplies used in modifying the vehicle and not incorporated into, attached to, or installed in the vehicle.

THIS SECTION INCORPORATES THE LANGUAGE WHICH PRECLUDES EXEMPTION FROM TAX SET FORTH IN THE FIRST PARAGRAPH OF EXISTING SECTION 1591(I). LANGUAGE IS ADDED TO PROVIDE EXAMPLES OF NON-EXEMPT ITEMS AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0168.175, 425.1117,

(e) Definitions

(1) 4 The term, “physically handicapped” persons, as used in this section, includes disabled persons described in Vehicle Code Section 22511.5 as qualified for special parking privileges.

(2) 2 The term, “vehicle, as used in this section, includes all devices which qualify under Vehicle Code Section 670 as “vehicles” including but not limited to automobiles, vans, trucks, mobilehomes and trailer coaches.

(3) 3 “Vehicles” qualifying under this section mean and include:

(A) Vehicles which are owned and operated by physically handicapped persons.

(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 22511.5 if the vehicle were registered to the physically handicapped person or persons.

EXISTING LANGUAGE IS INCORPORATED INTO A SEPARATE PARAGRAPH ON DEFINITIONS FOR CONSISTENCY IN DRAFTING

~~(m) MEDICAL OXYGEN SYSTEMS. Tax does not apply to the sale of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. "Medical oxygen delivery systems" includes liquid oxygen containers, high pressure cylinders, regulators, oxygen concentrators, tubes, masks, and related items necessary for the delivery of oxygen to the person. The term also includes repair and replacement parts for use in such a system.~~

Regulation 1591.7 ~~(n)~~ Medical Insurance

The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

THIS LANGUAGE IS ADDED HERE TO REFLECT THE REFORMATTING OF THE REGULATION INTO NEW COMPONENT SECTIONS

Regulation 1591.8 ~~(o)~~ Employer Medical Contracts.

Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated condition. one of which may be that no charge is to be made to the employee for prescribed medicines. The agreement may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

THIS LANGUAGE IS ADDED HERE TO REFLECT THE REFORMATTING OF THE REGULATION INTO NEW COMPONENT SECTIONS.

Regulation 1591.9 ~~(p)~~ Records

(a) Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section ~~4334~~ 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities. In addition, Government Code Section 15618 authorizes the Board's staff to examine prescription records for the purpose of determining compliance with the Sales and Use Tax Laws

NEW LANGUAGE IS ADDED TO INDICATE THE CURRENT BUSINESS AND PROFESSIONS CODE SECTION RELATING TO THE MAINTENANCE OF PHARMACY RECORDS, TO REFLECT CURRENT ANNOTATIONS AND TO REFLECT DIVISION OF EXISTING SECTION 1591 INTO NEW COMPONENT SECTIONS.

ANNOTATIONS 425.0007, 425.0023

(b) Pursuant to Section ~~4054~~ 4081 of the Business and Professions Code, licensed physicians and podiatrists must keep accurate records of drugs furnished by them. Government Code Section 15618 authorizes the Board's staff to examine prescriber's records for the purpose of determining compliance with the Sales and Use Tax Laws.

NEW LANGUAGE IS ADDED TO INDICATE THE CURRENT BUSINESS AND PROFESSIONS CODE SECTION, AND TO REFLECT CURRENT ANNOTATIONS

ANNOTATIONS 425.0007, 425.0023

ATTACHMENT 1

(c) Any deduction on account of sales of medicines shall be supported by appropriate records.

1. The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Section 6369: name of purchaser, name of doctor, date of sale, item sold, and the sales price.

2. “Double Deduction” Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

3. Persons making purchases of items exempt under this regulation should give their suppliers an exemption certificate to Regulation 1667.

THIS SECTION IS INCORPORATED HERE FOR CONSISTENCY IN THE REVISION AND REFORMATTING PROCESS INTO NEW COMPONENT SECTIONS

NOTE: Section 1591.5(b) does not mention “dentists”. Reference to “fully worn” in previous draft of 1591.5(b)(2) was deleted. The statutes do not use the term “fully worn” only “worn” on the body. Some of the quoted annotations include the “fully worn” requirement.

California Regulation, Reg. 1591. **Medicines and Medical Supplies, Devices and Appliances.--**

(a) *General.* Tax applies to retail sales of drugs, medicines, and other tangible personal property by pharmacists and others except as follows:

Tax does not apply to sales of medicines for the treatment of a human being which medicines are:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) hemodialysis products supplied on order of a licensed physician to a patient by a registered pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to a hemodialysis patient, or

(7) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (a)(7) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(8) furnished by a pharmaceutical company for the treatment of a human being during any phase of the Food and Drug Administration's drug development and approval process under the supervision of a licensed physician. The exemption provided by this subdivision (a)(8) applies to the constituent elements and ingredients used to produce the medicines,

to the tangible personal property which becomes a component part of the drug delivery system, and the material used to package such medicines.

(b) *Definition of "Medicines"*. The term "Medicines" means and includes:

(1) any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

(2) Bone screws, bone pins, pacemakers, and other articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body. The term also includes sutures, whether or not permanently implanted. A nonreturnable, nonreusable needle fused or prethreaded to a suture is regarded as a part of the suture.

(3) Artificial limbs, or their replacement parts, for human beings including stump stocks and stockings worn with an artificial leg.

(4) Orthotic devices, or their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure; provided, that orthopedic shoes and supportive devices for the foot are not exempt unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device which is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology. The device described above excludes

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; and

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

"Orthotic devices" includes, but is not limited to, abdominal binders, ace bandages, ankle braces, anti-embolism stockings, casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, support hose (and garter belts used to hold them in place), trusses, and wrist and arm braces.

(5) Prosthetic devices, or their replacement parts, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body, other than auditory, ophthalmic and ocular devices or appliances, and other than dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth and other dental prosthetic materials and devices.

(6) Artificial eyes, or their replacement parts, intraocular lenses for human beings and ear implants.

(7) Programmable or controlled drug infusion delivery devices, including those to be worn on, or implanted in, the human body, which automatically cause the infusion delivery of measured quantities of a medicine into or onto the body of the wearer or user of the device, and the devices that are necessary for the proper placement of such devices into the body or to connect them with the body's tissues.

(8) devices that incorporate or contain medicines, and which are necessary to the delivery or use of such medicines into, or onto, the body of a human being in conjunction with the diagnosis, treatment or prevention of disease.

~~(8) drugs furnished by a pharmaceutical company for the treatment of a human being during any phase of the Food and Drug Administration's drug development and approval process under the supervision of a licensed physician.~~

(c) *Exclusions from Term "Medicines"*. Except as otherwise provided in (b)(2) through (b)(7)(8) above, the following items are excluded from the term medicines:

(1) Orthodontic, prosthetic, auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).

(d) *Who Is a "Registered Pharmacist"*. A "registered pharmacist" is defined under Section 4036 of the Business and Professions Code as follows:

“ ‘Registered pharmacist’ means a person to whom a license has been issued by the board, under the provisions of Section 4200, except as specifically provided otherwise in this chapter.”

(e) *What Constitutes a “Prescription”*. Section 4040 of the Business and Professions Code defines “prescription” as follows:

“ ‘Prescription’ means an oral, written, or electronic transmission order that is both of the following: (1) Given individually for the person or persons for whom ordered that includes all of the following: (A) The name or names and address of the patient or patients. (B) The name and quantity of the drug or device prescribed and the directions for use. (C) The date of issue. (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed. (E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients. (F) If in writing, signed by the prescriber issuing the order. (2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian licensed in this state.”

No person other than a licensed physician, dentist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being.

(f) *Licensed Physician, Dentist or Podiatrist*. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge therefor to patients.

(g) *Health Facility*. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, . . .”

Tax does not apply to sales by a health facility of medicines for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales to a health facility of medicines for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(h) *Insulin*. “Insulin” and “insulin syringes” furnished by a registered pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369.

(i) *Orthotic and Prosthetic Devices*. Orthotic and prosthetic devices, and replacement parts for these devices, furnished pursuant to the written order of a licensed physician or podiatrist, shall be deemed to be dispensed on prescription within the meaning of paragraph (a)(1), whether or not the devices are furnished by a registered pharmacist.

(j) *Mammary Prostheses and Ostomy Appliances and Supplies*. Mammary prostheses, and any appliances and related supplies necessary as the result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste, shall be deemed to be dispensed on prescription within the meaning of Section 6369. Qualifying mammary prostheses and ostomy appliances and supplies include, but are not limited to, bras to hold a mammary prostheses in place, filler pads, lymphedema arm sleeves, adhesive spray and remover, belts, catheters used as a result of an artificial opening created in the human body, colostomy bags, deodorant used on the person of the user, karaya rings, antacid used externally as a skin ointment, skin gel, nonallergic paper tape and gauze, skin bond cement, tincture of benzoin applied topically as a protective, urinary drainage appliances, closed stoma bags, drainable stoma bags, loop ostomy supplies, and tubing.

The term “appliances” and “related supplies” includes kidney dialysis machines, and the tubing, pumps, blood sets, fistula sets, and shunts used in conjunction with such machines.

(k) *Wheelchairs, Crutches, Canes, Quad Canes and Walkers*. Tax does not apply to sales, including leases that are “sales”, of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, and walkers and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician.

(l) *Modifications to Vehicles Used by Physically Handicapped Persons*. Tax does not apply to the sale of items and materials used to modify a vehicle for physically handicapped persons which are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. The exemption does not extend to tools and supplies used in modifying the vehicle and not incorporated into, attached to, or installed on the vehicle.

In the case of a sale of a modified vehicle to a physically handicapped person, tax does not apply to the gross receipts attributable to that portion of the vehicle which has been modified to enable the vehicle to be used to transport a physically handicapped person or persons.

(1) The term, “physically handicapped” persons, as used in this section, includes disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.

(2) The term, “vehicle,” as used in this section, includes all devices which qualify under Vehicle Code Section 670 as “vehicles” including but not limited to automobiles, vans, trucks, mobilehomes and trailercoaches.

(3) “Vehicles” qualifying under this section mean and include:

(A) Vehicles which are owned and operated by physically handicapped persons.

(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.

(m) *Medical Oxygen Delivery Systems.* Tax does not apply to the sale of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. “Medical oxygen delivery systems” includes liquid oxygen containers, high pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the person. The term also includes repair and replacement parts for use in such a system.

(n) *Balloon Catheters.* Sales of intra-aortic balloon pump catheters and coronary angioplasty balloon catheters are not subject to tax. Sales of related supplies are subject to tax. The term “related supplies” includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, hemostatic valves, inflation devices, and syringes.

(o) *Medical Insurance.* The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(p) *Employer Medical Contracts.* Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated condition, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(q) *Records*. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4331 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to Section 4051 of the Business and Professions Code, licensed physicians and podiatrists must keep accurate records of drugs furnished by them.

Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Section 6369:

- Name of purchaser
- Name of doctor
- Date of sale
- Item sold
- The sale price

(2) “Double Deduction” Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Note:

Authority: Section 7051, Revenue and Taxation Code.

References:

Sections 6006, 6369, 6369.1, 6369.2, 6369.4, and 6369.5, Revenue and Taxation Code.

History:

- Amended September 26, 1979, effective November 16, 1979.
- Amended October 18, 1983, effective November 18, 1983.
- Amended October 26, 1993, effective February 17, 1994 (Register 94, No. 3).
- Amendment effective August 23, 1996.
- Amendment effective December 19, 1996.
- Amendment filed September 17, 1998, effective October 17, 1998.